

GLOBAL POINT OF CARE: STRATEGIES FOR DISASTER, EMERGENCY, AND PUBLIC HEALTH RESILIENCE, INCLUDING EBOLA!

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in collaboration with
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Please email questions to Dr. Kost at gjkost@ucdavis.edu. Thank you.



***Point-of-Care Testing Center
for Teaching and Research***



Global Point of Care

Strategies for Disasters, Emergencies, and Public Health Resilience

Edited by
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&
Corbin M. Curtis

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NEEDS ASSESSMENT FOR RAPID DECISION MAKING IN PANDEMICS, COMPLEX EMERGENCIES, AND DISASTERS: A GLOBAL PERSPECTIVE

GERALD J. KOST, RICHARD F. LOUIE, ANH-THU TRUONG, AND CORBIN M. CURTIS

OVERVIEW

Clinical needs assessment defines unmet healthcare needs and determines how to fill them. The goal of this chapter is to describe the process of performing needs assessment in the context of translating needs into innovative point-of-care (POC) technologies. We performed need assessment surveys to identify diagnostic testing gaps in complex emergencies, disasters, and public health and used SurveyMonkey® to administrate them. Literature searches also were conducted using the PubMed database and keywords, such as point of care, needs assessment, and POC disaster needs assessment. An emerging technology logic model summed up our approach. Original research by the University of California, Davis POC Technologies Center and publications by other investigators revealed insights about POC testing (POCT) needs for emergency and disaster response. Laboratorians, POC coordinators, medical doctors, researchers, disaster responders, disaster experts, and others indicated the importance of (a) having specific POC tests in emergencies and disasters, (b) desired sampling methods that preserve integrity of the sample while minimizing biohazard risks, and c) defined essential test clusters for bloodstream and respiratory infections. Evidence also revealed strong need for influenza testing and resistance markers useful in public health. Developers can reduce product development risks by conducting formal needs assessment that helps identify end-user product features and requirements early on. Needs assessment guides the product development pipeline of new technologies by helping (a) to identify and prioritize diagnostic testing needs, (b) to determine technological gaps and deficiencies that impact patient care, and (c) to design specifications for new POC technologies. Needs assessment has been successfully applied to identify POC diagnostic testing in complex emergencies, disasters, and public health as illustrated in this review and therefore can be used broadly in the point of care field to accelerate progress.

Based on a 2012 World Health Organization Health Statistics report, a median of 61% of the world health expenditure was paid by the government in 2009 (1). Needs assessment can reduce global health care expenditures, improve healthcare resource, and enhance standards of care. Needs assessment, per se, represents a systematic process for determining and addressing what POC users want, as well as for discovering gaps and deficiencies in the current delivery and practice of diagnostic testing at the sites of decision making (2).

Fundamentally, POCT grew out of satisfying clinical needs for bedside glucose testing, coagulation monitoring, and intensive care, where the advent of ionized calcium (Ca^{2+} , free calcium; Figure 1-1) (3, 4) proved that whole-blood analysis (5) was necessary for the diagnosis and treatment of critically ill patients with rapid therapeutic turnaround time (3) that could not be accomplished with centrifuged samples processed distantly in the conventional clinical laboratory. Once speed was achieved within a comprehensive value proposition of convenience, impactful bedside information, and improved outcomes, the paradigm of testing shifted to the point-of-need where it is likely to remain.

Enhanced healthcare delivery in complex emergencies and disasters can improve crisis standards of care (6). The Southeast Asia Tsunami in 2004, Hurricane Katrina in 2006, Haiti Earthquake in 2010, and Sandy Superstorm in 2012 disrupted, flooded, and destroyed infrastructure, including hospital laboratories and microbiology testing services thereby prolonging patient treatment (7–9). Public health officials should understand the methods of needs assessment, its importance, and current healthcare delivery models in order to push developers to deliver appropriate POC technologies that will enhance standards of care (6).

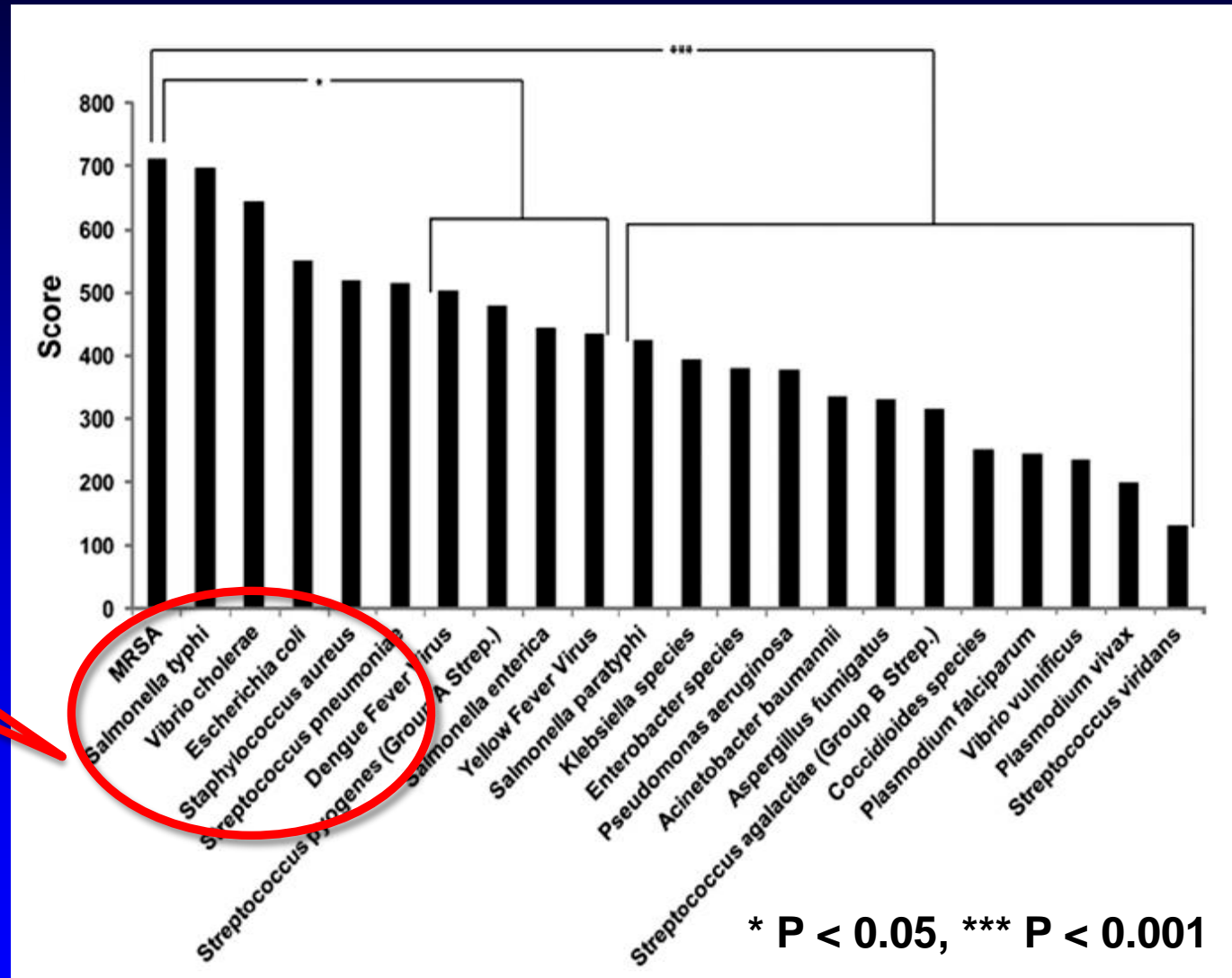
Strategically integrated POCT can provide rapid diagnostic data, facilitate triage, and improve management of victims during disasters (10). POC is testing performed at or near the site of the patient care (11). Recent disasters have demonstrated the feasibility of POCT, but POC devices lack crucial test clusters and are vulnerable to harsh disaster environments (12–22). The goal of this chapter is to describe the process of performing needs assessment in the context of translating needs into innovative POC technologies.

LEARNING OBJECTIVES

- **To demonstrate how to determine needs:** Needs assessment helps define the role of POCT in pandemics, complex emergencies, and disasters.
- **To understand environmental stresses:** Environmental stresses affect test results and must be avoided, so that POCT can be effective for decision-making in crises.
- **To illustrate the design of POCT caches:** Disaster caches should be designed and harmonized for collaborative use throughout the world, in part, to address new threats.
- **To introduce the Spatial Care Path™ (SCP) and point of care culture:** Spatial Care Paths™ start with the patient, position POCT optimally, and accelerate care, while we “tune the system” for cultural acceptance, so that national POCT policy and guidelines in limited-resource settings will enhance and sustain community resilience.

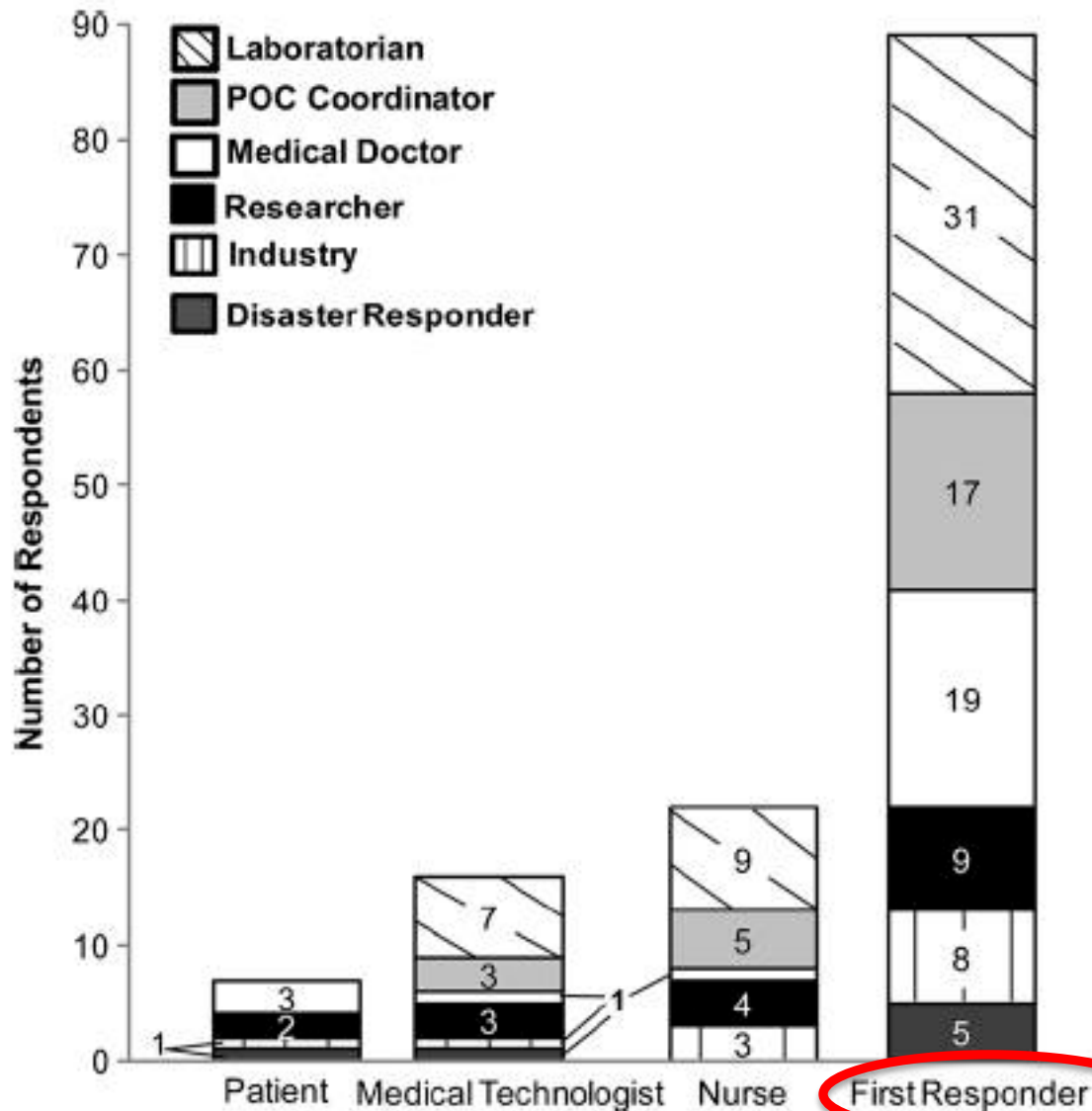
Needs Assessment Results from AACCC members

Top five pathogens selected for disaster settings



Reference: Kost GJ, et al. Assessing point-of-care device specifications and needs for pathogen detection in emergencies and disasters. *Point of Care*. 2012;11:119-125.

Needs Assessment Results from AACC members

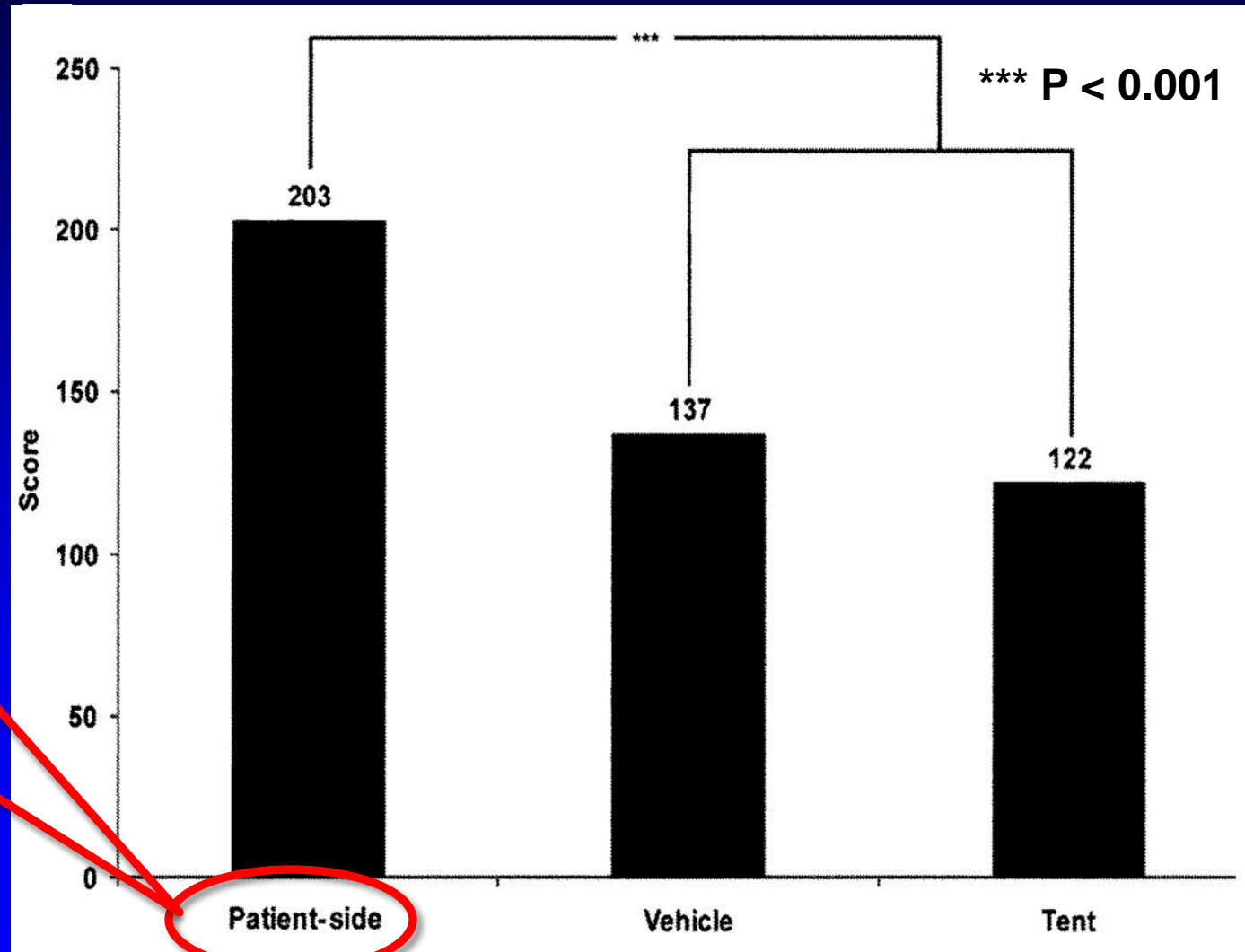


First Responders are the preferred group to perform POC testing in disasters

Reference: Kost GJ, et al. Assessing point-of-care device specifications and needs for pathogen detection in emergencies and disasters. *Point of Care*. 2012;11:119-125.

Needs Assessment Results from POC Journal Readers

Field Testing Location

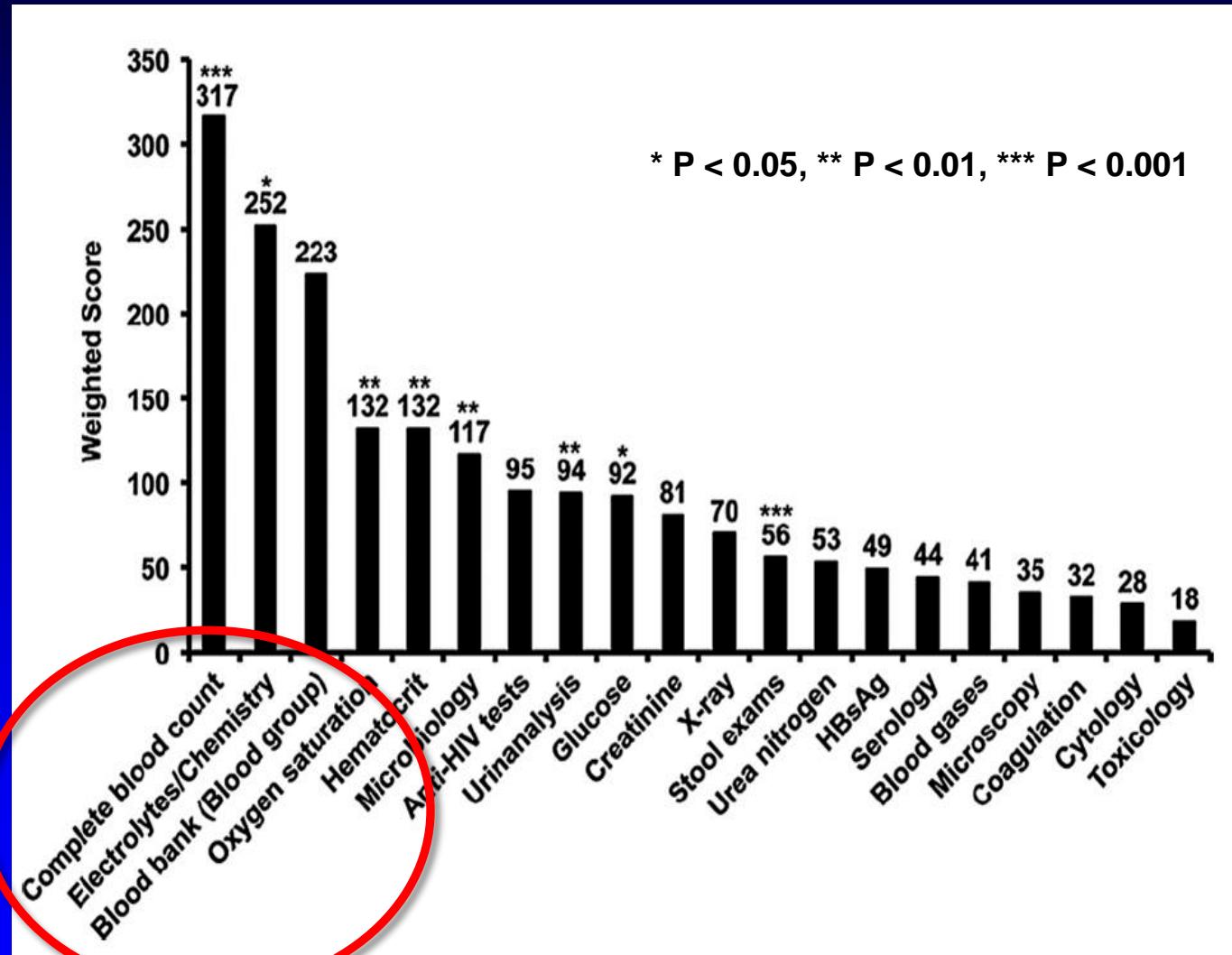


Respondents preferred patient-side testing in the field over testing inside a vehicle or tent.

Reference: Brock TK, et al. Evidence-based point-of-care tests and device designs for disaster preparedness. *Am J Disaster Med.* 2010;5:285-294.

Tsunami Needs Assessment Survey Results Phang Nga Coastal Province, Thailand

Respondents chose **CBC, Lytes/Chemistry, Blood Bank, & O₂ Saturation** as the highest priority diagnostic tests for a disaster



Reference: Kost GJ, et al. Strategic point-of-care requirements of hospitals and public health for preparedness in regions at risk. *Point of Care*. 2012;11:114-119.

How To: Monitor O₂ Saturation & Hemoglobin

**Cordless, Fingertip
Post-Tsunami, Thailand**
(Nonin Onyx II 9550)



O2 Pulse Oximeters for adult and neonate
(Nellcor OxiMax N-600x)



Embedded Printer
(BCI FingerPrint)



**Pulse Oximeter with
Bluetooth Module**
(Alive Pulse Oximeter)

**wireless connectivity
perfusion index
hemoglobin**
(Masimo Pronto 7)



**plethsmograph variability index
hemoglobin
carboxyhemoglobin
methemoglobin
perfusion index**
(Masimo Rad-57)



Tsunami Needs Assessment Survey Results

Pathogen Detection Must Flex for Future!

Different pathogens targeted for each objective. Now, N7N9, MERS CoV, & Ebola—moving targets, produce flexible devices!

TABLE 1. Pathogen Test Menus for Emergency and Disaster Care

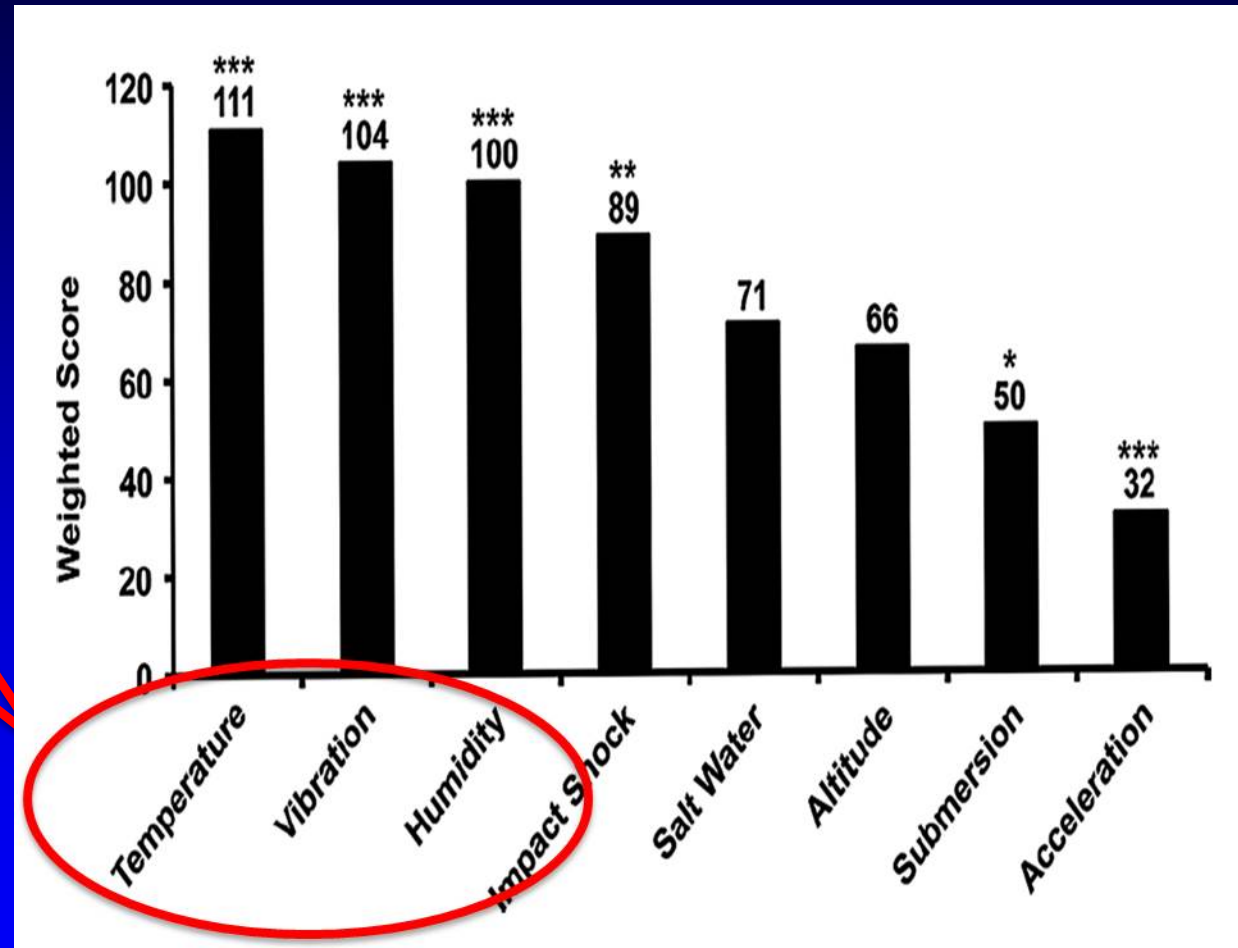
Objective	Weighted Score	Pathogen	Objective	Weighted Score	Pathogen
(A) Civil disaster infections (n = 24)	52	<i>S. aureus</i>	(C) Bloodstream infections (n = 24)	95	<i>S. pneumoniae</i>
	42	<i>Klebsiella</i> sp		85	<i>S. aureus</i>
	41	Dengue fever virus		75	<i>Escherichia coli</i>
	36	<i>Pseudomonas aeruginosa</i>		72	<i>Pseudomonas aeruginosa</i>
	34	Human immunodeficiency virus types 1 and 2		65	<i>Streptococcus</i> sp
	30	Hepatitis B virus		52	<i>Klebsiella</i> sp
	28	<i>Enterobacter</i> sp		48	Methicillin-resistant <i>S. aureus</i>
	23	<i>Vibrio cholerae</i>		43	<i>Enterobacter</i> sp
	23	<i>Plasmodium vivax</i>		31	<i>Acinetobacter baumannii</i>
	20	<i>Plasmodium falciparum</i>		30	Coagulase-negative <i>Staphylococcus</i>
	18	<i>Streptococcus pyogenes</i>			
(B) Respiratory pandemics (n = 24)	60	SARS	(D) Emergency blood donor screening (n = 24)	155	Hepatitis B virus
	60	Avian influenza (H5N1)		150	Human immunodeficiency virus types 1 and 2
	45	Respiratory syncytial virus		138	Hepatitis C virus
	43	<i>S. pneumoniae</i>		68	Epstein-Barr virus
	42	Influenza A/B virus		61	Dengue fever virus
	41	<i>Mycobacterium tuberculosis</i>		57	Cytomegalovirus
	37	<i>Haemophilus influenzae</i>		49	Parvovirus B19
	35	<i>Mycoplasma pneumoniae</i>		49	Chikungunya virus
	34	<i>S. aureus</i>		43	Human T-cell lymphotropic virus 1 and 2 (HTLV 1 and 2)
	33	<i>Klebsiella</i> sp			
	26	Pandemic (H1N1) 2009 influenza			

Reference: Kost GJ, et al. Strategic point-of-care requirements of hospitals and public health for preparedness in regions at risk. *Point of Care*. 2012;11:114-119.

Tsunami Needs Assessment Survey Results

Environmental Stresses

Respondents chose 3 physical challenges as the most important environmental factors to overcome in future POC device designs for extreme conditions



Reference: Kost GJ, et al. Strategic point-of-care requirements of hospitals and public health for preparedness in regions at risk. *Point of Care*. 2012;11:114-119.



Hurricane Katrina, 2005



Haiti Earthquake, 2010



Christchurch, New Zealand, 2011



Japan Earthquake / Tsunami, 2011

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THE IMPACT OF ENVIRONMENTAL STRESS ON DIAGNOSTIC TESTING AND IMPLICATIONS FOR PATIENT CARE DURING CRISIS RESPONSE

**RICHARD F. LOUIE, WILLIAM J. FERGUSON, CORBIN M. CURTIS, ANH-THU TRUONG, MANDY H. LAM,
AND GERALD J. KOST**

OVERVIEW

Strategic integration of point-of-care (POC) diagnostic tools during crisis response can accelerate triage and improve management of victims. Timely differential diagnosis is essential wherever care is provided to rule out or rule in disease, expedite life-saving treatment, and improve utilization of limited resources.

POC testing (POCT) needs to be accurate in any environment in which it is used. Devices are exposed to potentially adverse storage and operating conditions, such as high and low temperature and humidity during emergencies and field rescues. Therefore, characterizing environmental conditions allows technology developers, operators, and responders to understand the broad operational requirements of test reagents, instruments, and equipment in order to improve the quality and delivery of care in complex emergencies, disasters, and austere environmental settings.

This chapter aims (a) to describe the effects of environmental stress on POCT performance and its impact on decision making; (b) to describe how to study the effects; and (c) to summarize approaches to minimize or nullify the effects of environmental stresses through good laboratory practice, development of robust reagents, and producing novel thermal packaging solutions.

ENVIRONMENTAL STRESSORS AND POC TESTING

In crisis response, strategic integration of POC diagnostic tools, such as portable multiplex cardiac biomarker testing, at alternate care facilities can accelerate triaging and improve management of victims (1). Timely differential diagnosis is essential wherever care is provided to rule out or rule in disease, expedite appropriate life-saving treatment, and improve utilization of limited resources (1).

Between 1980 and 2013, the United States experienced 640 disaster events. Of those events 64.5% (413/640) were weather related (2). Deaths associated with weather-related events account for 87.8% of all disaster deaths (2). Table 23-1 (3–5) summarizes the environmental conditions observed in recent disasters. With careful implementation and integration of POC tests for onsite triaging and diagnosis, lives potentially could have been saved.

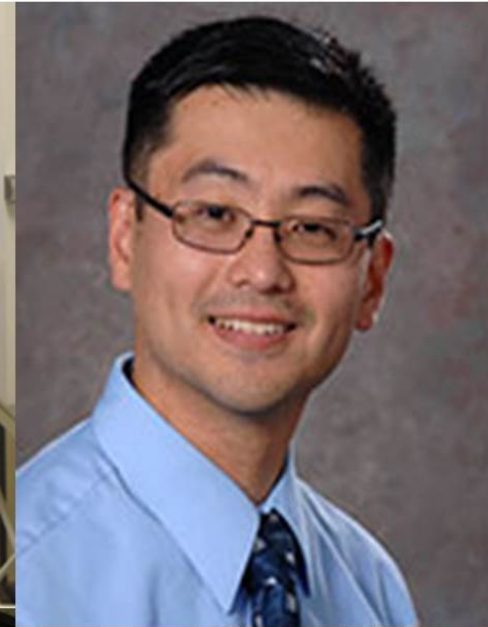
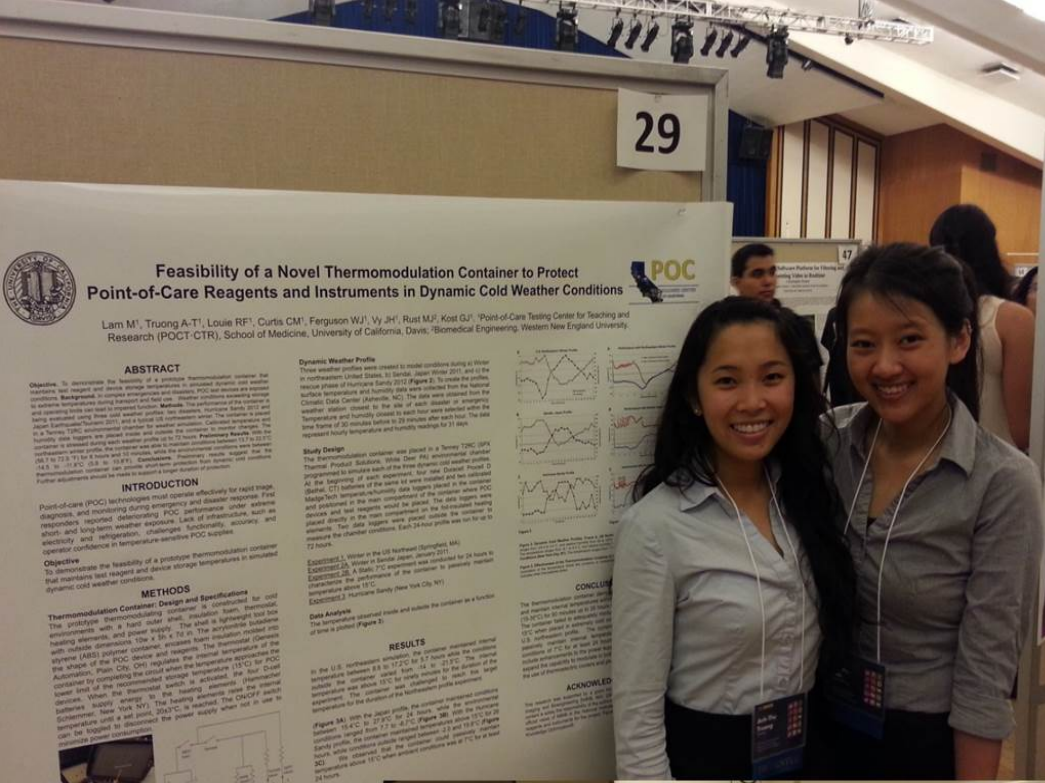
To ensure accurate and safe use, POCT needs to deliver excellent performance in any environment in which it is used (6). Erroneous results can cause serious harm and alter clinical decision making, such as improper insulin dosage (7). Emergency and disaster responders equipped with POC technologies for rapid triage, diagnosis, and monitoring must function effectively in adverse conditions. These conditions may exceed the storage and operating specifications of both POC test reagents and the instruments.

Tables 23-2, and 23-3 (8) summarize the storage and operating specifications of select POC devices. Test reagents typically are refrigerated or stored in ambient conditions between 15–30°C (59–86°F). Reagents requiring refrigeration can be stored at ambient conditions (e.g., room temperature), but are then stable for a shorter duration. The US Pharmacopeia defines room temperature as 20–25°C (68–77°F) with allowable short-term excursions spanning 15–30°C (59–86°F), and a mean kinetic temperature (MKT) not more than 25°C (77°F).

Mean Kinetic Temperature.

MKT, a simplified way of expressing the overall temperature impact on first-order chemical reactions, weighs the effects of temperature variations over an extended period of time according to the following equation (9):

$$MKT = \frac{\Delta E / R}{-\ln \left(\frac{e^{\left(\frac{-\Delta E}{RT_1} \right)} + e^{\left(\frac{-\Delta E}{RT_2} \right)} + \dots + e^{\left(\frac{-\Delta E}{RT_n} \right)}}{n} \right)}$$



Dynamic Temperature and Humidity Environmental Profiles: Impact for Future Emergency and Disaster Preparedness and Response

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Keywords: mean kinetic temperature; point-of-care; weather profiles

Abbreviations:

BNP: B-type natriuretic peptide
Ca²⁺: calcium
CK-MB: creatine-kinase MB isoform
CTnI: cardiac troponin I
K⁺: potassium
MKT: mean kinetic temperature
MYO: myoglobin
Na⁺: sodium
PCO₂: partial pressure of carbon dioxide

Abstract

Introduction: During disasters and complex emergencies, environmental conditions can adversely affect the performance of point-of-care (POC) testing. Knowledge of these conditions can help device developers and operators understand the significance of temperature and humidity limits necessary for use of POC devices. First responders will benefit from improved performance for on-site decision making.

Objective: To create dynamic temperature and humidity profiles that can be used to assess the environmental robustness of POC devices, reagents, and other resources (eg, drugs), and thereby, to improve preparedness.

Methods: Surface temperature and humidity data from the National Climatic Data Center (Asheville, North Carolina USA) was obtained, median hourly temperature and humidity were calculated, and then mathematically stretched profiles were created to include extreme highs and lows. Profiles were created for: (1) Banda Aceh, Indonesia at the time of the 2004 Tsunami; (2) New Orleans, Louisiana USA just before and after Hurricane Katrina made landfall in 2005; (3) Springfield, Massachusetts USA for an ambulance call during the month of January 2009; (4) Port-au-Prince, Haiti following the 2010 earthquake; (5) Sendai, Japan for the March 2011 earthquake and tsunami with comparison to the colder month of January 2011; (6) New York, New York USA after Hurricane Sandy made landfall in 2012; and (7) a 24-hour rescue from Hawaii USA to the Marshall Islands. Profiles were validated by randomly selecting 10 days and determining if (1) temperature and humidity points fell inside and (2) daily variations were encompassed. Mean kinetic temperatures (MKT) were also assessed for each profile.

Results: Profiles accurately modeled conditions during emergency and disaster events and enclosed 100% of maximum and minimum temperature and humidity points. Daily variations also were represented well with 88.6% (62/70) of temperature readings and 71.1% (54/70) of relative humidity readings falling within diurnal patterns. Days not represented well primarily had continuously high humidity. Mean kinetic temperature was useful for severity ranking.

Conclusions: Simulating temperature and humidity conditions clearly reveals operational challenges encountered during disasters and emergencies. Understanding of environmental stresses and MKT leads to insights regarding operational robustness necessary for safe and accurate use of POC devices and reagents. Rescue personnel should understand these principles before performing POC testing in adverse environments.

Ferguson WJ, Louie RF, Tang CS, Paw U KT, Kost GJ. Dynamic temperature and humidity environmental profiles: impact for future emergency and disaster preparedness and response. *Prehosp Disaster Med.* 2014;29(1):4-12.

PO₂: partial pressure of oxygen
POC: point of care

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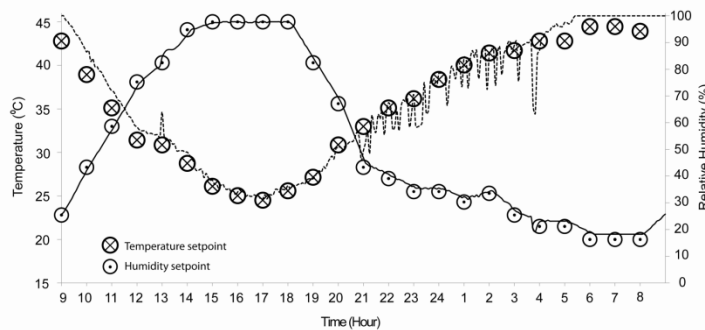
doi:10.1017/S1049023X13009199

Environmental Stress Testing Workflow

POC Reagent Test Strips & Cartridges



Environmental Stress Testing Chamber & Profile



Test Stressed Strips & Cartridges



- Facilitate Device Design
- Enhance Guidelines Development for POCT in Emergency and Disaster Settings

ORIGINAL RESEARCH

Effects of Dynamic Temperature and Humidity Stresses on Point-of-Care Glucose Testing for Disaster Care

Richard F. Louie, PhD; William J. Ferguson; Stephanie L. Sumner; Jimmy N. Yu; Corbin M. Curtis; Gerald J. Kost, MD, PhD, MS

ABSTRACT

Objective: To characterize the performance of glucose meter test strips using simulated dynamic temperature and humidity disaster conditions.

Methods: Glucose oxidase- and glucose dehydrogenase-based test strips were dynamically stressed for up to 680 hours using an environmental chamber to simulate conditions during Hurricane Katrina. Paired measurements vs control were obtained using 3 aqueous reagent levels for GMS1 and 2 for GMS2.

Results: Stress affected the performance of GMS1 at level 1 ($P < .01$); and GMS2 at both levels ($P < .001$), lowering GMS1 results but elevating GMS2 results. Glucose median-paired differences were elevated at both levels on GMS2 after 72 hours. Median-paired differences (stress minus control) were as much as -10 mg/dL (range, -65 to 33) at level 3 with GMS1, with errors as large as 21.9%. Glucose median-paired differences were as high as 5 mg/dL (range, -1 to 10) for level 1 on GMS2, with absolute errors up to 24.4%.

Conclusions: The duration of dynamic stress affected the performance of both GMS1 and GMS2 glucose test strips. Therefore, proper monitoring, handling, and storage of point-of-care (POC) reagents are needed to ensure their integrity and quality of actionable results, thereby minimizing treatment errors in emergency and disaster settings. (*Disaster Med Public Health Preparedness*. 2012;6:232-240)

Key Words: disaster preparedness, Hurricane Katrina, medical errors, austere environments, quality assurance

During emergencies and disasters, point-of-care testing (POCT) facilitates patient triage with rapid screening and monitoring tests at the site of care, such as the field, an alternate care facility, or an emergency department.¹ Emergency responders need to be prepared to manage acute diseases and injuries, such as infections and trauma, and provide care for displaced victims with chronic ailments, such as diabetes.

POCT devices, such as glucose meter systems (GMS), are found in caches of disaster response teams. During Hurricane Katrina, shortages of diabetes supplies (eg, medicine, glucose test strips and meters) have been reported.² Emergency responders are deployed to a variety of environments where conditions often may exceed the reagent and device storage and operating tolerance limits.

We hypothesize that dynamic temperature and humidity stresses affect the performance of glucose meter test strips. Therefore, the objective of this report is to characterize the performance of two commercial glucose test strips using a dynamic stress profile that models conditions in New Orleans during Hurricane Katrina.

METHODS

Point-of-Care Systems and Reagents

GMS1 is a glucose oxidase-based electrochemical meter system, and GMS2 is a glucose dehydrogenase-based meter system. Glucose meters and aqueous quality control

solutions (QC) were stored and operated within manufacturer's specifications, at room temperature ($19.7 \pm 0.6^\circ\text{C}$, range 18.8 to 23.0°C) and at relative humidity ($46.4 \pm 12.8\%$, range 21% to 77%). A subset of single-use disposable reagent test strips from each GMS was stressed with an environmental testing chamber (Tenney T2RC, Thermal Products Solution) that was programmed to simulate conditions during Hurricane Katrina. Stressed strips were tested immediately after removal from the chamber in pairs with control (unstressed) strips. Control strips were stored at room temperature.

We used aqueous QC solutions supplied by the manufacturers to test performance. QC solutions are proprietary reagents manufactured by each company to allow the operator to check if the test strips and meter are working properly. The QC solutions typically are composed of glucose, buffer, dyes, salts, preservatives, and viscosity-adjusting agents. Three levels of QC were used for testing GMS1, and two levels of QC were used for testing GMS2.

Environmental Profile

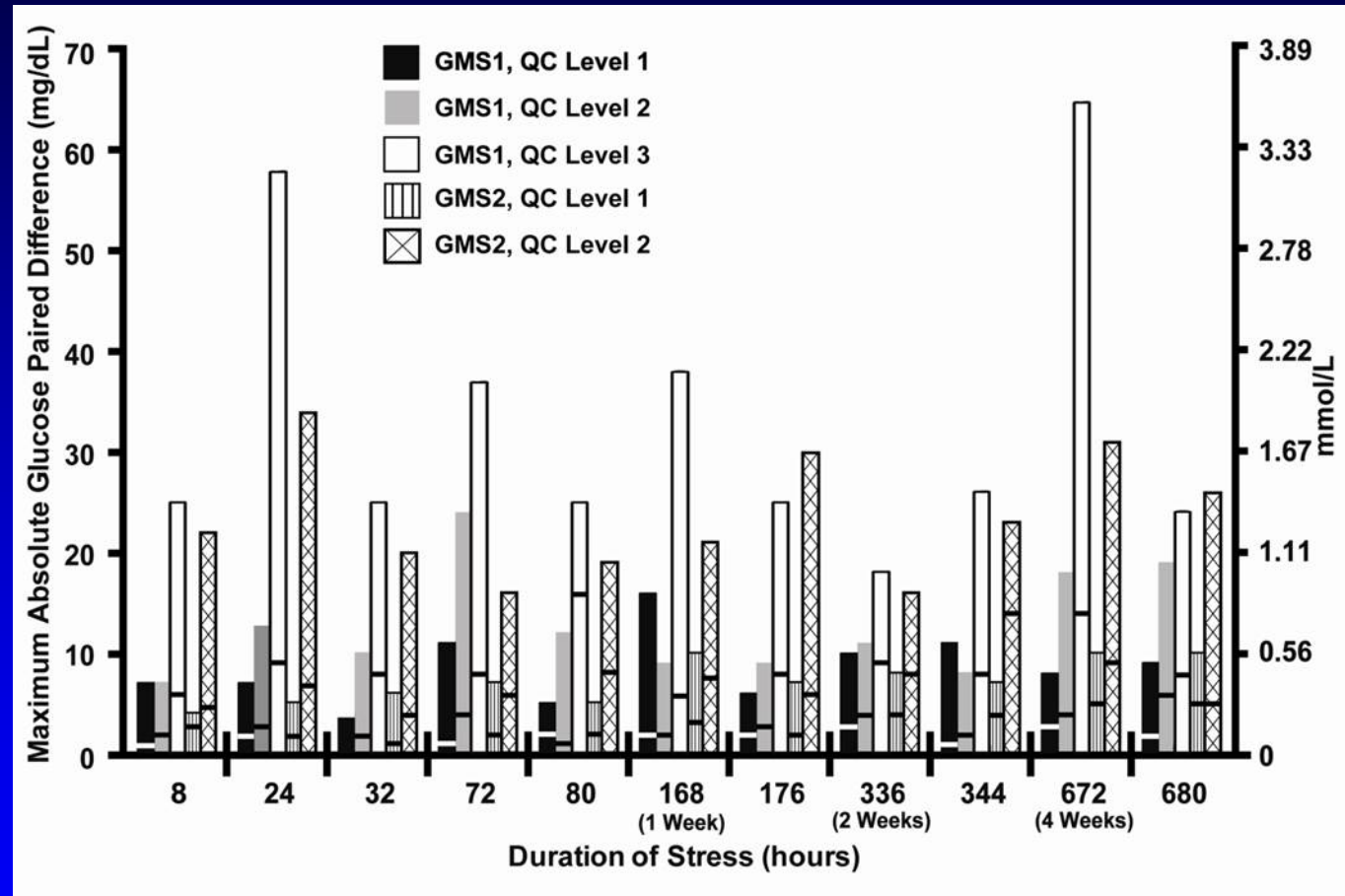
We modeled the dynamic thermal and humidity conditions of New Orleans, Louisiana, during Hurricane Katrina (Figure 1) with data collected over a 31-day period from the National Climatic Data Center (NCDC). Data were compiled from two weather stations, New Orleans/Moisant and Baton Rouge Metro. The Baton Rouge station supplied 1.5 days of missing values for the

Dynamic Temperature and Humidity Stress

- **Goal**—To characterize the effects of dynamic thermal and humidity stress on the performance of glucose meter measurements
- **Methods**—Glucose test strips were exposed to conditions simulating the temperature and humidity experienced in New Orleans following the Hurricane Katrina disaster for a duration of ~4 weeks
- **Statistical Model**—Paired measurements were obtained from stressed and unstressed glucose reagent strips at defined time points. Strips were tested with aqueous quality control solutions.
- **Results**—The duration of stress affected the performance of the glucose meter systems. One system provided lower measurements and the other elevated when stressed. As demonstrated on one system, the stress effects on test performance is cumulative with pronounce effect after 32 hours of exposure.

Maximum Absolute Paired Differences Between Stress & Control Glucose Test Strips

- For GMS1, errors as large as **27.6%** (16 mg/dL / 57.9 mg/dL) was observed when tested at mean glucose concentration of 57.9 mg/dL, **21.9%** (24/109.6) at 109.6 mg/dL, and **22.4%** (65/290.5) at 290.5 mg/dL.



- For GMS2, errors as large as **24.4%** (10/41) was observed when test at mean glucose concentration of 41.0 mg/dL, and **11.1%** (34/305.3) at 305.3 mg/dL

Short-Term Thermal-Humidity Shock Affects Point-of-Care Glucose Testing: Implications for Health Professionals and Patients

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Abstract

The objective was to assess the effects of short-term (≤ 1 hour) static high temperature and humidity stresses on the performance of point-of-care (POC) glucose test strips and meters. Glucose meters are used by medical responders and patients in a variety of settings including hospitals, clinics, homes, and the field. Reagent test strips and instruments are potentially exposed to austere environmental conditions. Glucose test strips and meters were exposed to a mean relative humidity of 83.0% (SD = 8.0%) and temperature of 42°C (107.6°F, SD = 3.2) in a Tenney BTRC environmental chamber. Stressed and unstressed glucose reagent strips and meters were tested with spiked blood samples ($n = 40$ measurements per time point for each of 4 trials) after 15, 30, 45, and 60 minutes of exposure. Wilcoxon's signed rank test was applied to compare measurements test strip and meter measurements to isolate and characterize the magnitude of meter versus test strip effects individually. Stressed POC meters and test strips produced elevated glucose results, with stressed meter bias as high as 20 mg/dL (17.7% error), and stressed test strip bias as high as 13 mg/dL (12.2% error). The aggregate stress effect on meter and test strips yielded a positive bias as high as 33 mg/dL (30.1% error) after 15 minutes of exposure. Short-term exposure (15 minutes) to high temperature and humidity can significantly affect the performance of POC glucose test strips and meters, with measurement biases that potentially affect clinical decision making and patient safety.

Keywords

clinical decision making, environmental stress, glucose test strip and meter performance, measurement error, patient safety, quality assurance

Glucose meter systems aid responders in triaging, screening, monitoring, and the diagnosis of victims and patients at the site of crisis care. Temperature and humidity conditions at the site of patient care, whether inside or outside the victims' home or hospital, may exceed manufacturer specifications for storage and operation. Operation of devices outside of product specifications could produce inaccurate results.

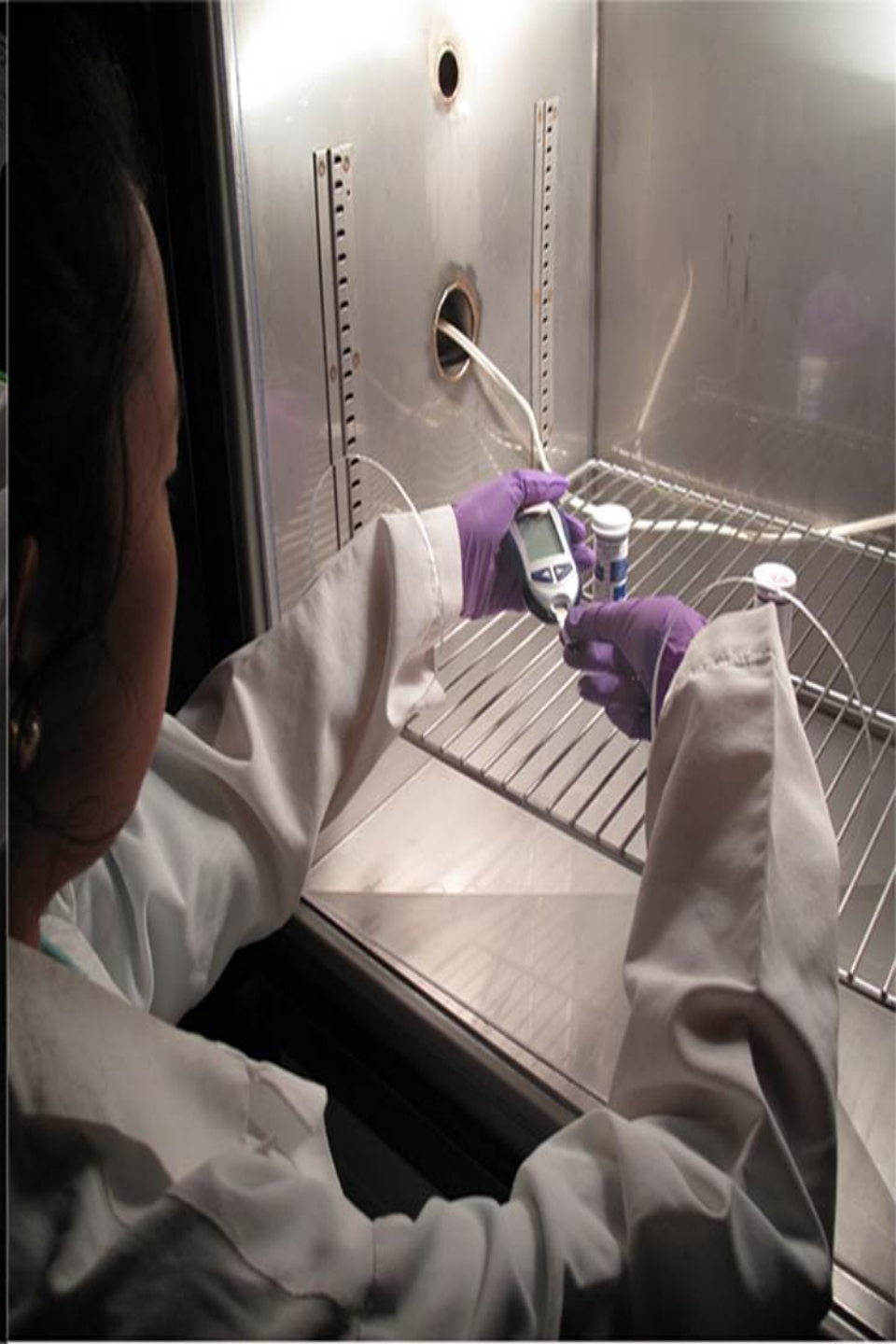
Point-of-care (POC) devices deployed with disaster response teams are recommended to be housed in climate controlled settings.¹ However, these devices may be exposed to austere conditions when mobilized for field testing. Temperature extremes can be found in a variety of settings including the patient's home, distinct geographic locations, and with the settings.

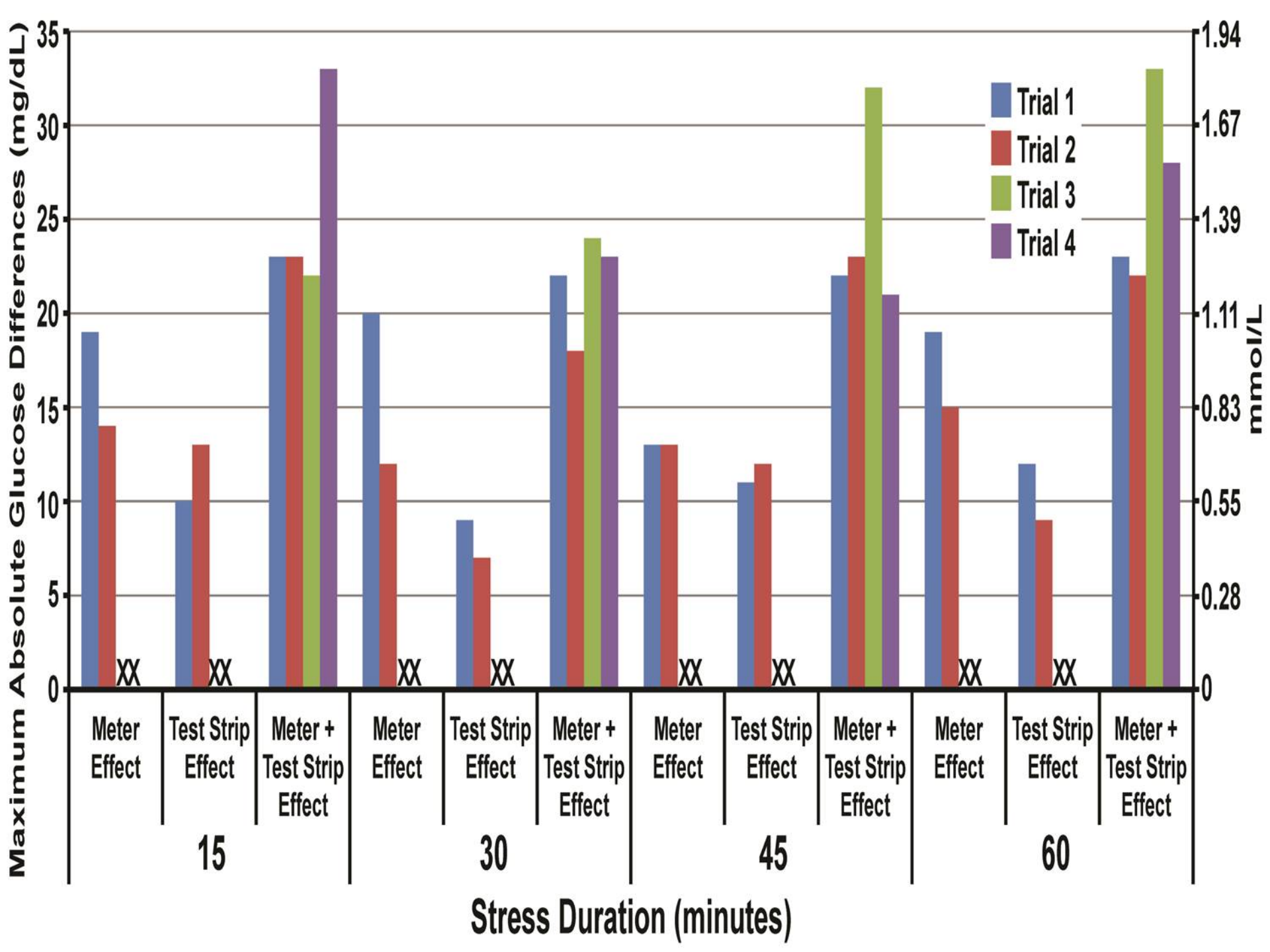
This study aims to simulate realistic operation of POC glucose devices in austere environments, to compare measurements obtained from unstressed devices and test reagents, and to characterize how short-term stress affects meter and test strip performance. We discuss the potential implications of these effects on clinical decision making.

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Effects of environmental conditions on point-of-care cardiac biomarker test performance during a simulated rescue: Implications for emergency and disaster response

Richard F. Louie, PhD, FACB; William J. Ferguson, BS; Corbin M. Curtis, BS; John H. Vy, BS; Chloe S. Tang, BS; Gerald J. Kost, MD, PhD, MS, FACB

Abstract

Objective: To characterize the effects of environmental stress on point-of-care (POC) cardiac biomarker testing during a simulated rescue.

Design: Multiplex test cassettes for cardiac troponin I (cTnI), brain natriuretic peptide (BNP), CK-MB, myoglobin, and D-dimer were exposed to environmental stresses simulating a 24-hour rescue from Hawaii to the Marshall Islands and back. We used Tenney environmental chambers (T2RC and BTRC) to simulate flight conditions (20°C, 10 percent relative humidity) and ground conditions (22.3-33.9°C, 73-77 percent). We obtained paired measurements using stressed versus control (room temperature) cassettes at seven time points (T_{1-7} with $T_{1,2,6,7}$ during flight and T_{3-5} on ground). We analyzed paired differences (stressed minus control) with Wilcoxon signed rank test. We assessed the impact on decision-making at clinical thresholds.

Results: cTnI results from stressed test cassettes ($n = 10$) at T_4 ($p < 0.05$), T_5 ($p < 0.01$), and T_7 ($p < 0.05$) differed significantly from control, when testing samples with median cTnI concentration of 90 ng/L. During the ground rescue, 36.7 percent (11/30) of cTnI measurements from stressed cassettes generated significantly lowered results. At T_5 , 20 percent (2/10) of cTnI results were highly discrepant—stressed cassettes reported normal results, when control results were >100 ng/L. With sample median concentration of 108 pg/mL, BNP results from

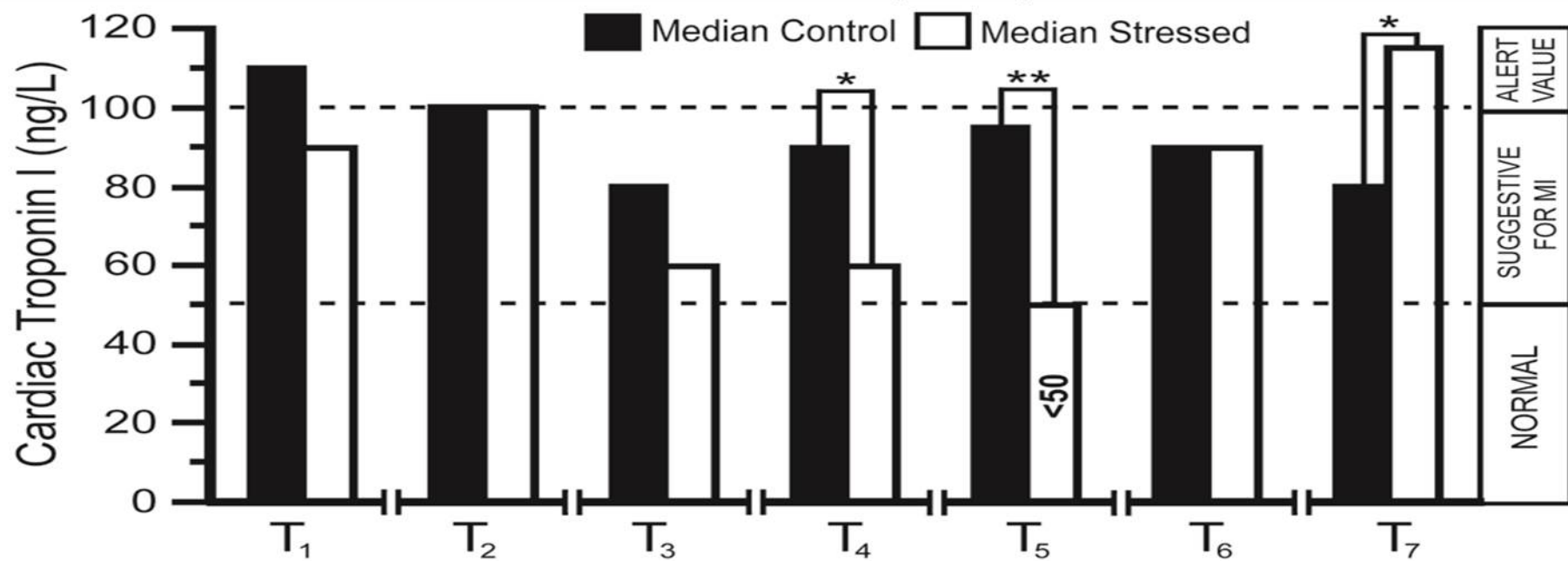
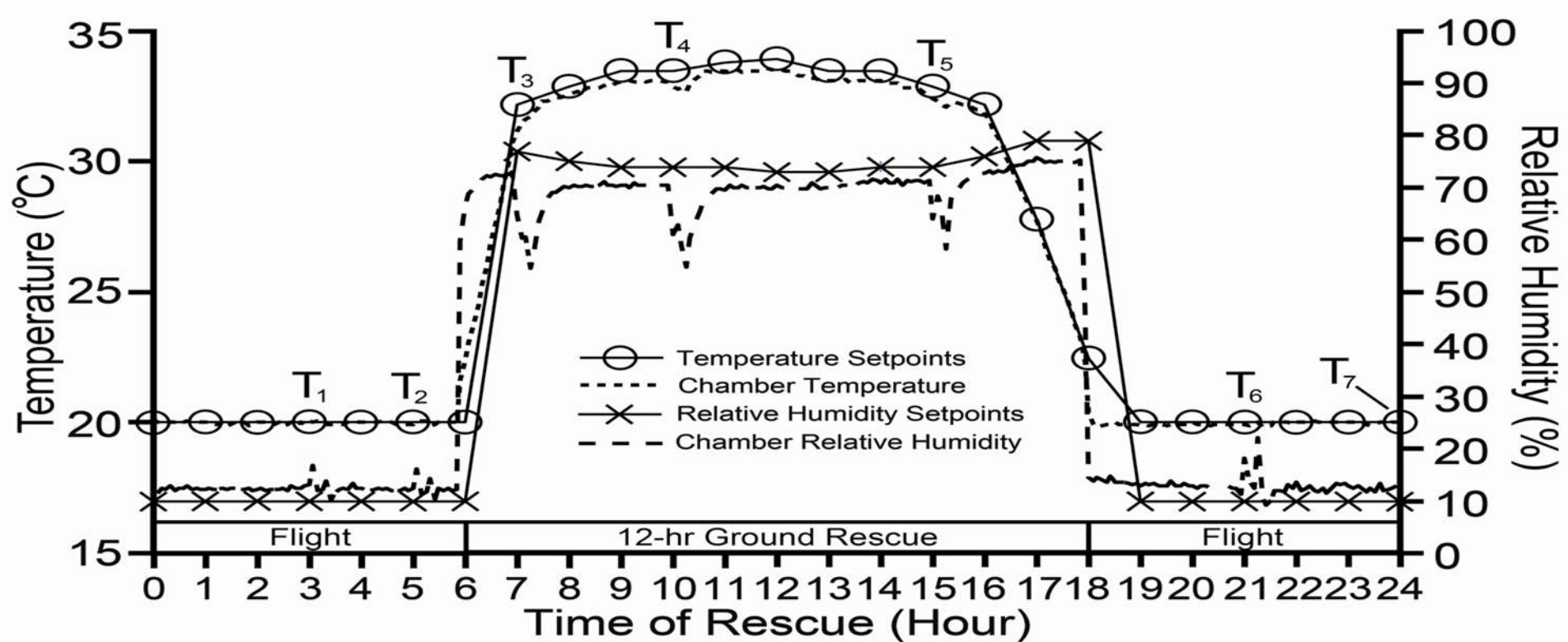
stressed test cassettes differed significantly from controls ($p < 0.05$).

Conclusion: Despite modest, short-term temperature elevation, environmental stresses led to erroneous results. False negative cTnI and BNP results potentially could miss acute myocardial infarction and congestive heart failure, confounded treatment, and increased mortality and morbidity. Therefore, rescuers should protect POC reagents from temperature extremes.

Key words: austere environments, disaster preparedness, medical errors, Pacific Islands, and quality assurance

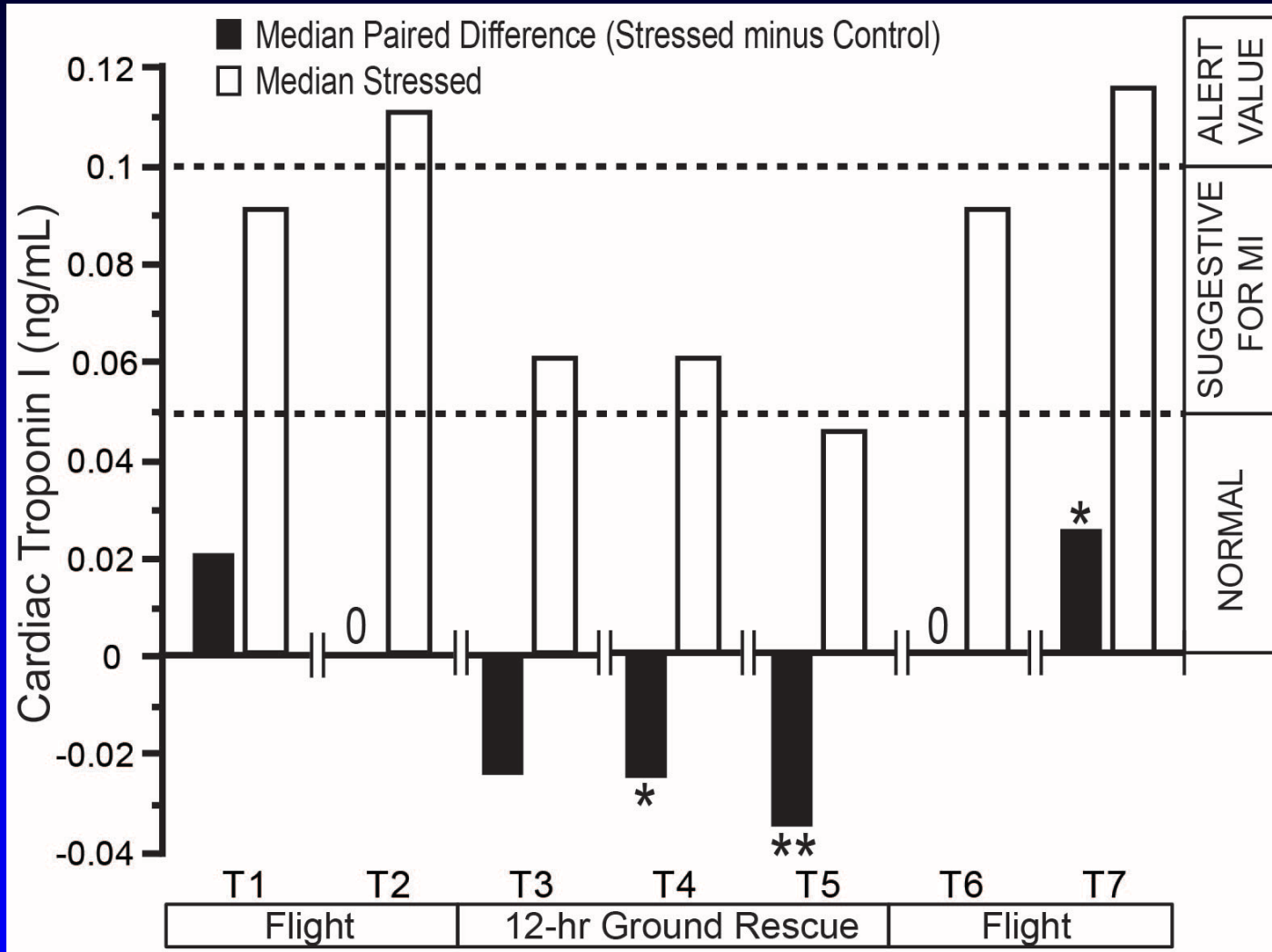
Introduction

Emergency medical responders are deployed with limited point-of-care (POC) tests during crises, which restricts triaging in the field. Quantitative measurement of cardiac troponin I (cTnI), brain natriuretic peptide (BNP), CK-MB, myoglobin, and D-dimer in whole blood and plasma specimens can aid in the diagnosis of myocardial infarction, heart failure, pulmonary embolism, and deep vein thrombosis. Environmental conditions present during rescue operations may exceed storage and operating specifications of POC devices and test reagents.¹⁻³ The objective of this study was to characterize the performance of POC cardiac biomarker tests in a simulated rescue between the Hawaiian Islands and Marshall Islands.



Effects of Stress on cTn I Test Results

- During ground rescue 36.7% (11/30) of stressed test cards reported falsely low cTnI results interpreted as “normal”
- At T₅, 20% (2/10) results were highly discrepant: stress <0.05, control ≥0.10 ng/mL
- Median stressed cTnI at T₅ was <0.05 ng/mL



- During the return flight, stressed cards reported falsely elevated cTnI >0.1 ng/mL at T₇, which in our emergency department “alerts” possible AMI.

Global Point of Care

Strategies for Disasters, Emergencies, and Public Health Resilience

Edited by
Gerald J. Kost
&
Corbin M. Curtis

AACCPress

THE CURRENT AND FUTURE DESIGN OF POINT OF CARE IN NATIONAL DISASTER CACHES

CORBIN M. CURTIS, RICHARD F. LOUIE, AND GERALD J. KOST

OVERVIEW

The objective of this chapter is to describe, innovate, recommend, and foster the implementation of point-of-care testing (POCT) in disaster caches in order to enhance crisis standards of care and improve triage, diagnosis, monitoring, treatment, and management of victims and volunteers in complex emergencies and disasters. The authors compared point-of-care (POC) technologies in US disaster caches to commercially available POC technologies to enhance the caches and reflect current state-of-the-art diagnostic capabilities. We also provided recommendations based on literature review and knowledge from newly developed POC technologies from the University of California, Davis Point-of-Care Technologies Center on designing POC caches applicable to meet global needs. US POC testing caches comprise chemistry/electrolytes, pregnancy, hemoglobin, cardiac biomarkers, hematology, fecal occult blood, drugs of abuse, liver function, blood gases, and limited infectious disease tests. Deficiencies with existing POCTs for cardiac biomarkers, hematology, and infectious diseases should be eliminated. POC resources can be customized for pandemics, complex emergencies, or disasters based on geographic location and the potential for pandemics. Additionally, new thermally stabilized containers can help alleviate environmental stresses that reduce test quality. Innovations in POC technologies can improve response preparedness with enhanced diagnostic capabilities. Several innovations, such as the *i-STAT*® Wireless (Abbott Point of Care, Princeton, NJ, USA), OraQuick *ADVANCE*® HIV-1/2 (OraSure Technologies,

Bethlehem, PA, USA), VereTrop™ Lab-on-a-Chip (Veredus Laboratories, Singapore), and new compact hematology analyzers will improve test clusters that facilitate evidence-based decision making and crisis standards of care during national disaster responses. Additionally, strategic resources and operator training should be globally harmonized to improve the efficiency of international responses.

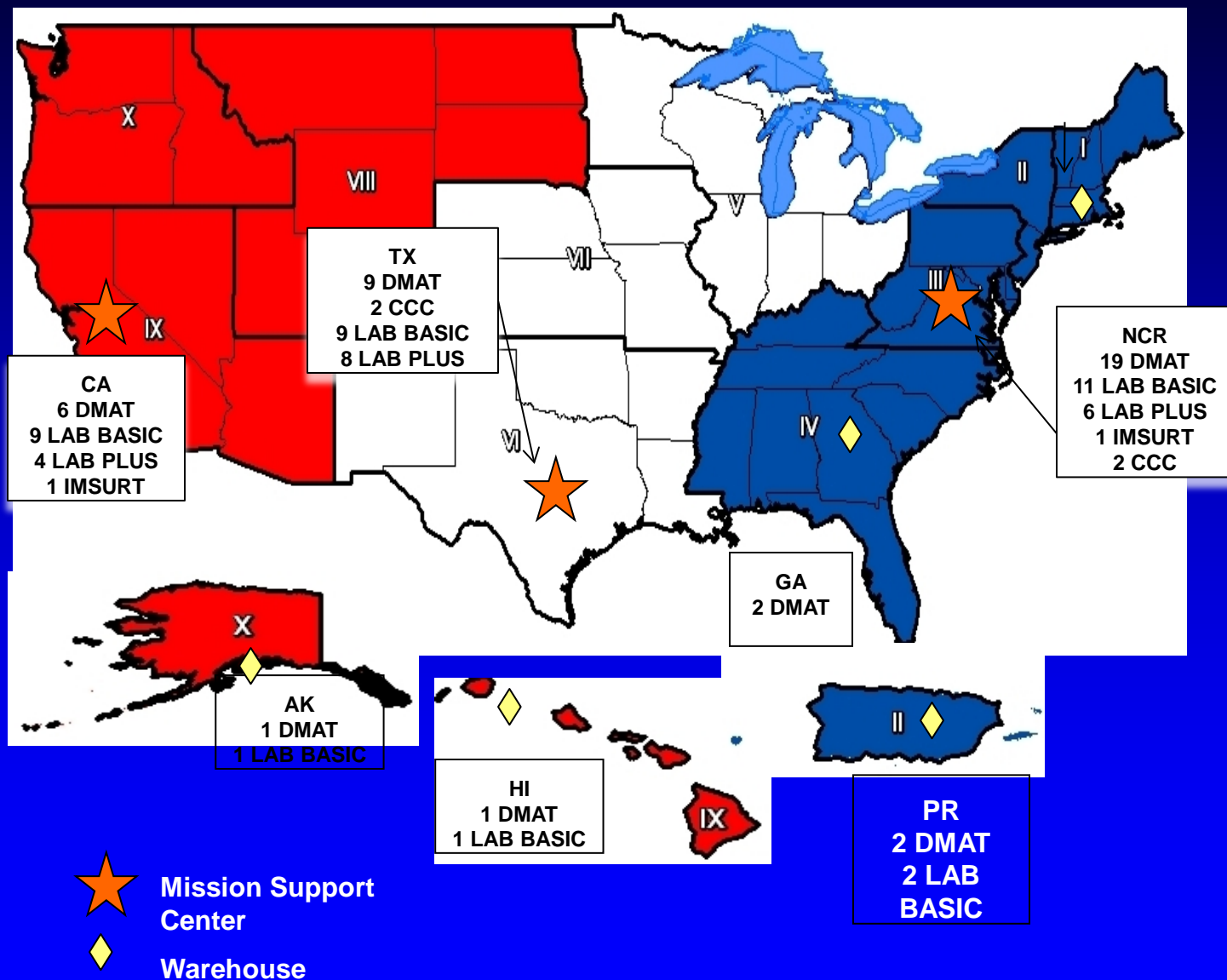
Our goal is to describe, innovate, recommend, and accelerate the implementation of POCT in disaster caches in order to (a) enhance crisis standards of care; (b) improve diagnosis, triage, and monitoring in complex emergencies and disasters; and (c) harmonize evidence-based decision making during responses globally. The Office of the Assistant Secretary for Preparedness and Response (ASPR) under the US Department of Health and Human Services (DHHS) maintains three Mission Support Centers (MSCs) located in the western, central, and eastern United States. The eastern region and largest cache warehouse (200,000 ft²)* serves as a training facility, home base for cache management, and national headquarters. Disaster response supplies deploy by trucks from any of the three locations to reach a disaster site in the contiguous United States or by airplane to sites outside the landlocked states such as Hawaii, Alaska, and the Republic of the Marshall Islands, within 12 h.

The caches within each facility hold supplies that Disaster Medical Assistance Teams (DMATs) use to triage, diagnose, and monitor victims following catastrophic events. Each facility has an inventory of pharmaceuticals, DMAT response packages, Basic Load Resupply packages to replenish 3 days of supplies for 175 patients per day, temporary portable housing, electricity generators, communication supplies, and vehicles to deliver resources to disaster sites where they converge with DMATs. The packages load straight onto trucks or airplanes without needing further organization. POC devices

This study was supported by the Point-of-Care Testing Center for Teaching and Research (POCT•CTR) and by a National Institute for Biomedical Imaging and Bioengineering (NIBIB) Point-of-Care Technologies Center grant (Dr. Kost, PI, NIH U54 EB007959). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIBIB or the National Institutes of Health.

*1 ft² = xxx m².

Locations of US National Caches



Lab Basic Kit



Lab Plus Kit



Disaster Point of Care



Wi-Fi



i-STAT® 1 Wireless with
G3+ (blood gases),
Chem 8+ (electrolytes), BNP,
and cTnI Cartridges



Oraquick ADVANCE®
HIV 1/2



Onyx® II 9560
Fingertip Pulse
Oximeter



Sure-Vue® Urine
hCG Cartridge

POC Hematology
Analyzer

WBC, Differential, RBC,
Plt, Hb, and Indices



Wi-Fi



QuickVue® Influenza Test



Rapid tests for
Strep Throat,
Mono and D-dimer



Hemocult®-Immunochemical
Fecal Occult Blood Test

Multistix® 10 SG
Urinalysis Strips
Bilirubin, Blood, Glucose,
Ketone, Leukocyte Esterase,
Nitrite, pH, Protein, Specific
Gravity, Urobilinogen



ABORhCard®
Blood Typing
Test Card

CoaguChek® XS Plus
System for PT/INR



Triage®
Drugs of Abuse
Test Card



StatStrip
Glucose, Lactate,
 β -hydroxybutyrate
and Creatinine



Masimo Rad-57™
Oxygen Saturation
and Hemoglobin
plus pediatric probes

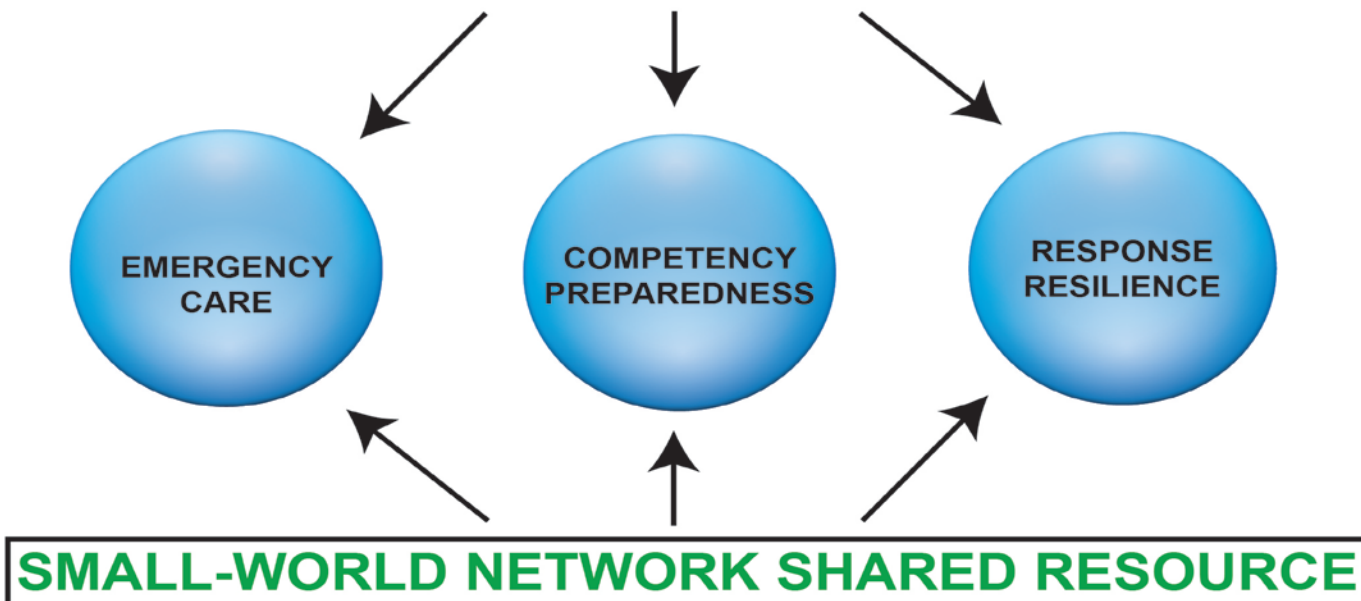


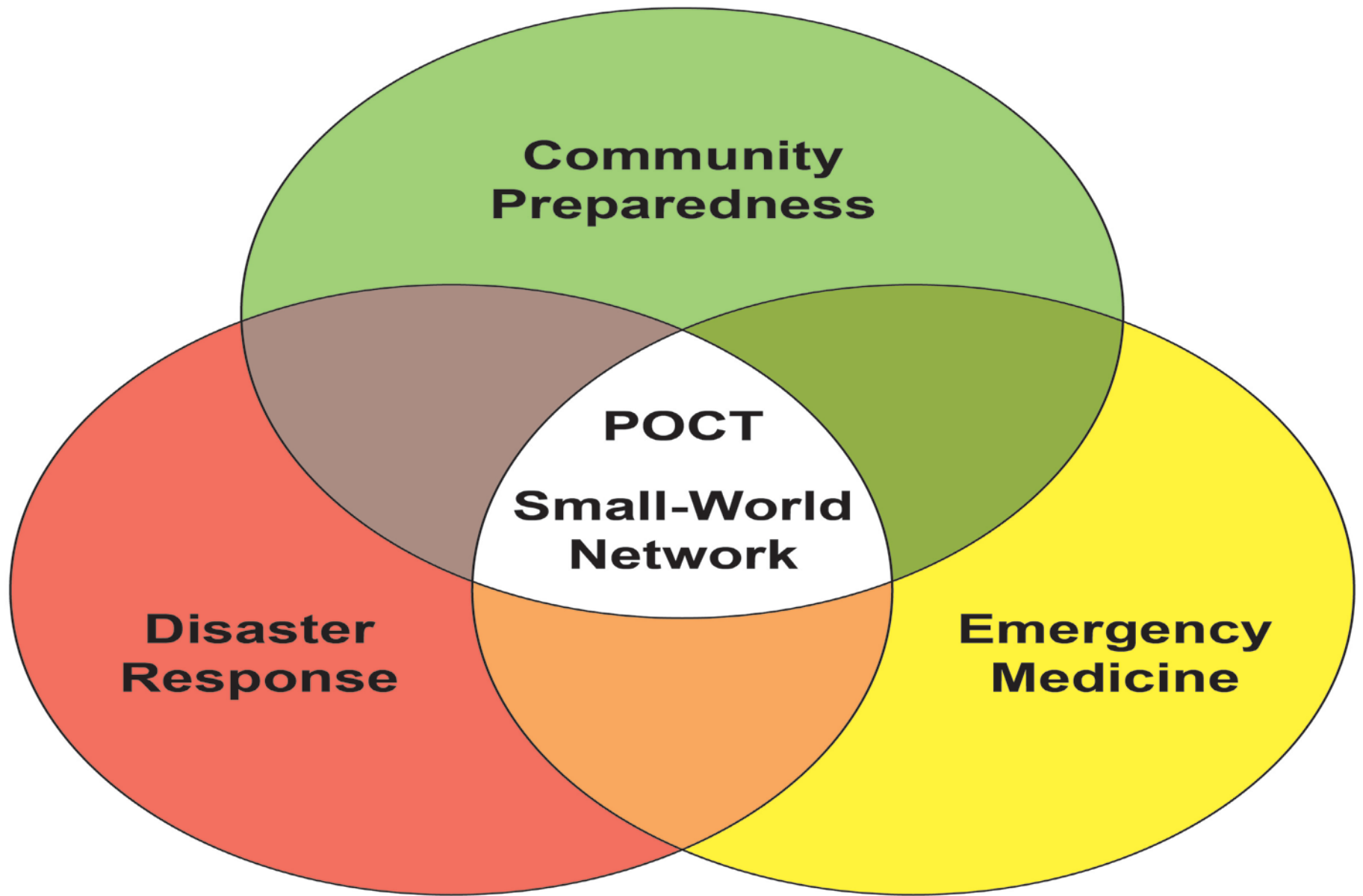
Min-Max
Temp



Patient Health Security Card

Disaster Point of Care





Reference: Kost GJ, Sakaguchi A, Curtis CM, Tran NK, Katip P, Louie RF. Enhancing crisis standards of care using innovative point-of-care testing. *Am J Disaster Med.* 2011;6:351-368.

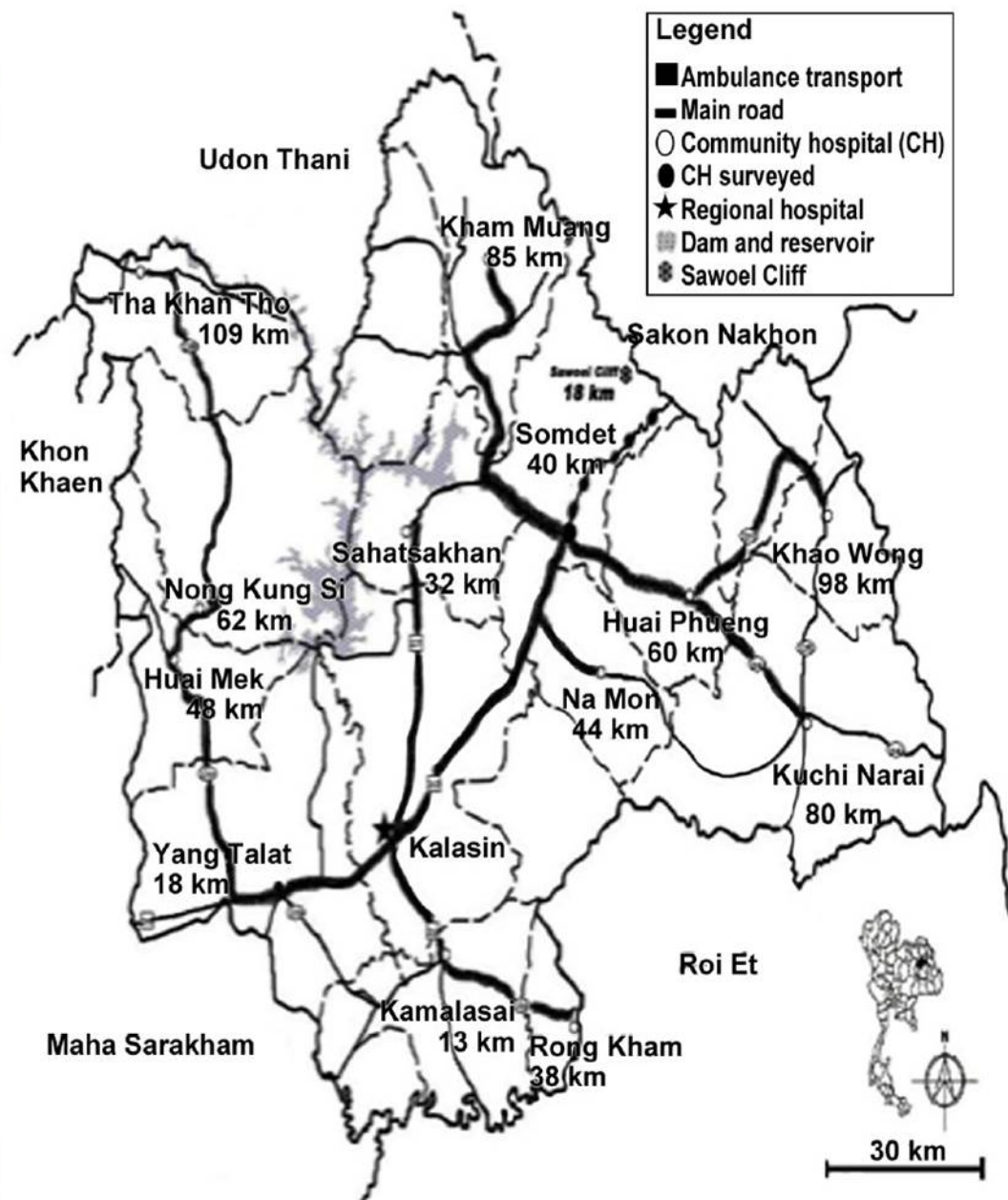
Drawing Kalasin and Marha Sarakham Province SWN ambulance routes

Kalasin:
above to
her right

Maha
Sarakham:
below to
her left



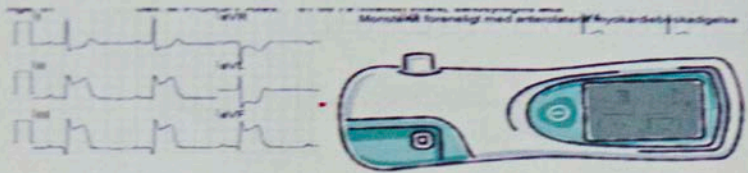
Critical paths (bold) of Kalasin Province SWN extracted from the ER RN's highlights (orange)



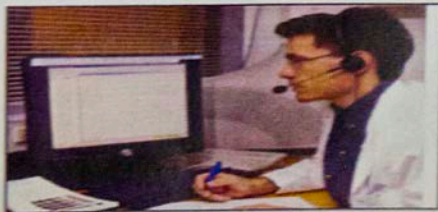
Prehospital Spatial Care Path™ for Acute Myocardial Infarction



1. The patient alerts emergency medical services.



2. An ECG is recorded and a blood test performed if there is suspicion of an acute myocardial infarction.



3. The results are transmitted wirelessly to the cardiologist on call.



4. The ambulance is directed to the invasive center or nearest coronary care unit, depending on the diagnosis.

Step 1. The patient alerts emergency services while at home or about.

Step 2. An ECG is recorded and a cardiac troponin T (or I) test is performed if there is suspicion of AMI.

Step 3. The ECG and cTnT test results are transmitted wirelessly to the cardiologist on call.

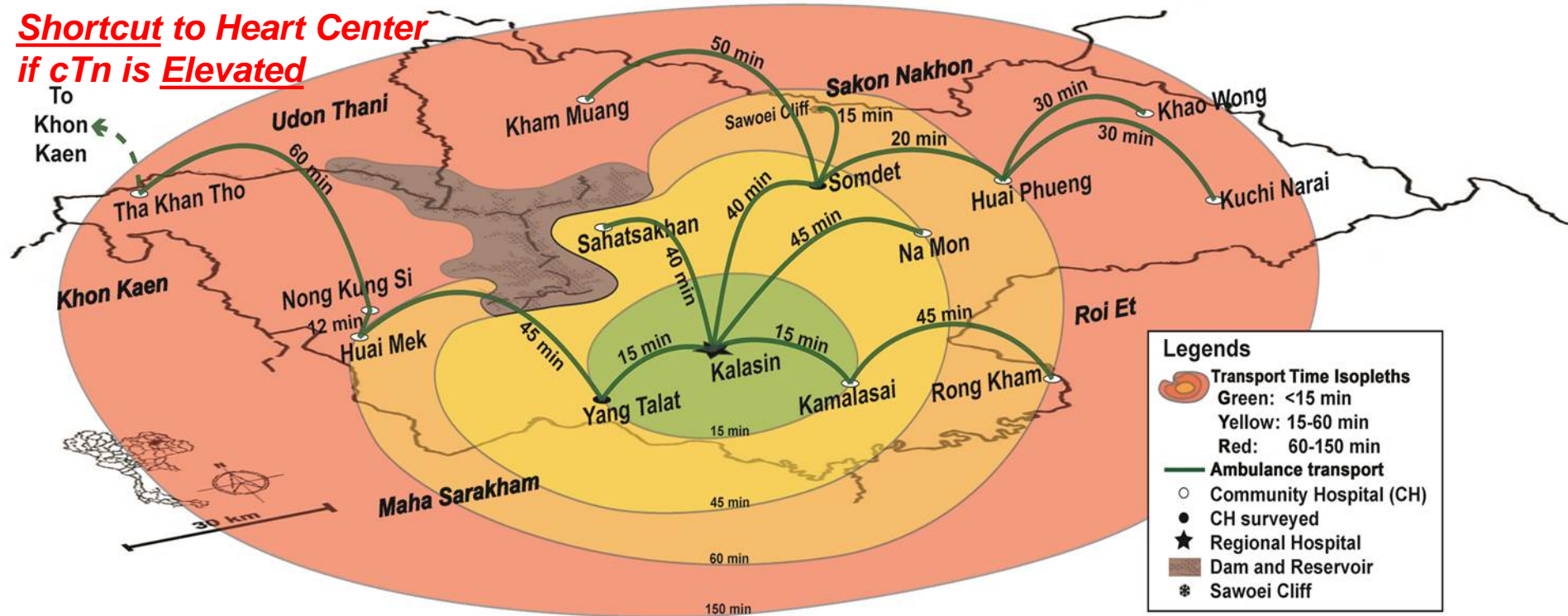
Step 4. The ambulance is directed to the invasive center or nearest coronary care unit, depending on the diagnosis.

Conclusion: “POCT performed by paramedics, nurses, or doctors can improve diagnostic accuracy where the ECG does not provide decisive information. This enables optimal triage and early aggressive treatment of patients who currently experience a very high mortality. Prehospital biomarkers provide strong prognostic information early on, allowing the ER to prepare optimally for patient arrival.”

From Sorensen JT and Stengaard C. Prehospital application of cardiac biomarkers for decision support in patients with suspected AMI. In: Kost GJ, Ed., *Global Point of Care*, 2015.

Transforming the Physical Domain to the Temporal Domain in Small-World Network Spatial Care Paths™

Shortcut to Heart Center
if cTn is Elevated



Reference: Kost GJ. Theory, principles, and practice of optimizing point-of-care small-world networks. *Point of Care*. 2012;11:96-101.

Principles of point of care culture, the spatial care path™, and enabling community and global resilience

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Laurie E. Kost, BS, MS^d

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^b Knowledge Optimization®, Davis, CA

^c Affiliate Faculty, College of Population Studies, Chulalongkorn University, Bangkok, Thailand

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ARTICLE INFO

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Running title

Enabling Community and Global Resilience

Key words

Care path, customs, decision-making,
empowerment, geographic information
systems (GIS), geography, intervention,
lifestyle, medical poverty, needs
assessment, point-of-care (POC)
technologies, POC testing, prevention,
public health jurisdictions, small-
world network, survey, and value

ABSTRACT

Goals: This article a) defines point of care (POC) culture; b) presents seven underlying fundamental principles; c) describes the importance of needs assessment; d) introduces a new innovation, the spatial care path™; and e) illustrates how POC testing that properly fulfills needs and spatial care paths™ enable community and global resilience.

Observations: Often, POC testing supplants the conventional clinical laboratory, which may be too distant, prohibitively expensive, or simply not available in limited-resource settings. New POC technologies “fit” future medical problem solving. Screening and testing directly in the home or primary care facilitate rapid diagnosis, monitoring, and treatment. In contrast to the past where attention has been placed on emergency departments, hospitals, and referral centers, the spatial care path™ starts with the patient and guides him or her through an efficient strategy of care in small-world networks (SWNs) defined by local geography and topology, long-standing customs, public health jurisdictions, and geographic information systems (GIS).

Conclusions: POC testing needs in limited-resource settings are striking. Fulfillment is best guided by thorough understanding of POC culture. Quick feedback and fast decision-making

**PUBLISHED IN
AUGUST,
2014;25(2):4-23.**

Online Access:
<http://www.ifcc.org/media/260912/eJIFCC%20August%202014.pdf>

THE SPATIAL CARE PATH™

- ***Definition:*** *The most effective route taken by the patient when receiving definitive care in a small-world network.*
- ***Hypothesis:*** *Common purpose in public health integrates prevention and intervention to shift focus upstream to the patient site in order to save resources, time, and lives.*
- ***Features:*** *Starts with the patient rather than the institution, empowers primary care, establishes critical access using geographic information systems, positions POCT, and optimizes decision-making, including unexpected crises.*
- ***Status:*** *Exploratory research—Thailand, Brazil, and others.*

Reference: Kost GJ, Ferguson WJ, Kost LE. Principles of point of care culture, the spatial care path™, and enabling community and global resilience. *e-JIFCC*. 2014;25(2):4-23.

Developing a Spatial Care Path™ for Ebola

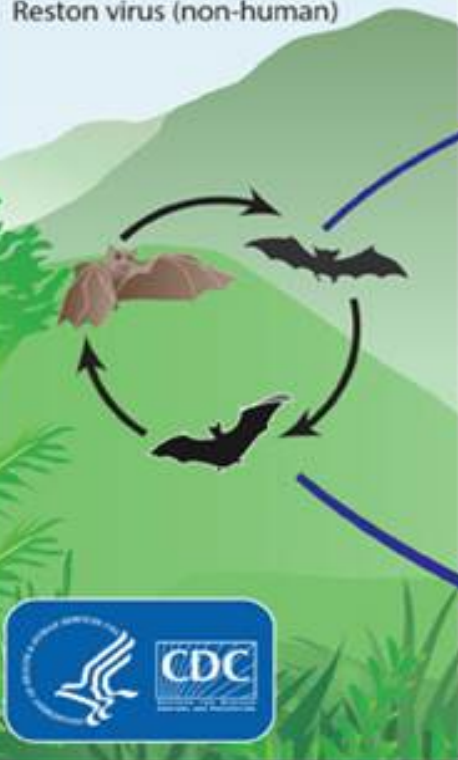


Enzootic Cycle

New evidence strongly implicates bats as the reservoir hosts for ebolaviruses, though the means of local enzootic maintenance and transmission of the virus within bat populations remain unknown.

Ebolaviruses:

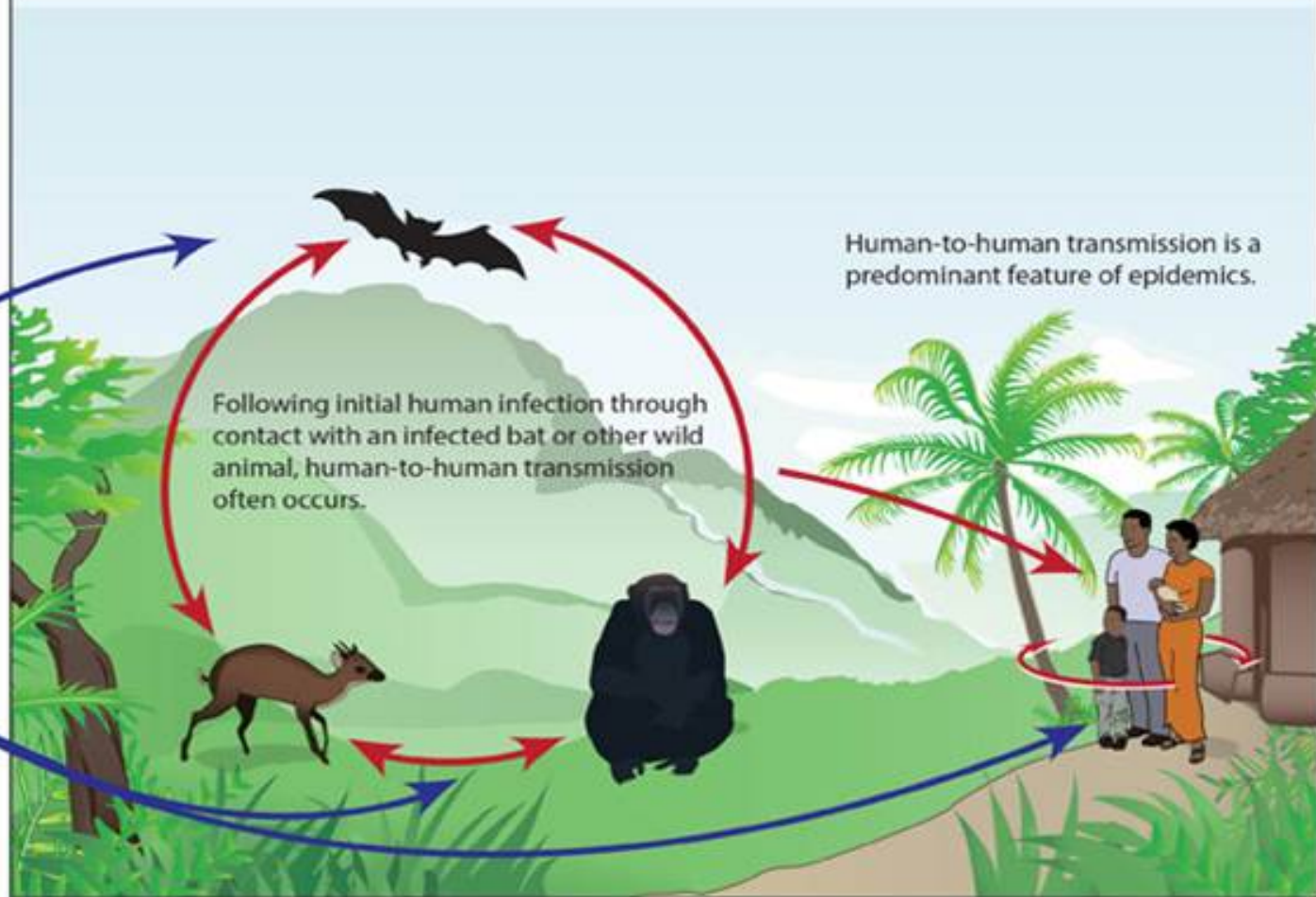
- Ebola virus (formerly Zaire virus)
- Sudan virus
- Tai Forest virus
- Bundibugyo virus
- Reston virus (non-human)



Epizootic Cycle

Epizootics caused by ebolaviruses appear sporadically, producing high mortality among non-human primates and duikers and may precede human outbreaks. Epidemics caused by ebolaviruses produce acute disease among

humans, with the exception of Reston virus which does not produce detectable disease in humans. Little is known about how the virus first passes to humans, triggering waves of human-to-human transmission, and an epidemic.



Laboratory Diagnosis of Ebola—Too Slow!

TIMELINE OF INFECTION

Within a few days after symptoms begin

Later in disease course or after recovery

Retrospectively in deceased patients

DIAGNOSTIC TESTS AVAILABLE

Antigen-capture enzyme-linked immunosorbent assay (ELISA) test

IgM ELISA

Polymerase chain reaction (PCR)

Virus isolation

IgM and IgG antibodies

Immunohistochemistry test

PCR

Virus isolation

“The Race to Diagnose”



Source: Baker A, Cape Town. *Time*. Vol. 184, No. 17, November 3, 2014, pages 28-29.

Corgenix received a \$2.9 million grant from the NIH in June.

Disposable test administered at a clinic, in the home, or during airport arrival.

Pinprick of blood from the finger of a patient.

Positive result indicated by a dark red line on the test strip.

Can only identify Ebola at symptom onset 8-10 days following exposure.

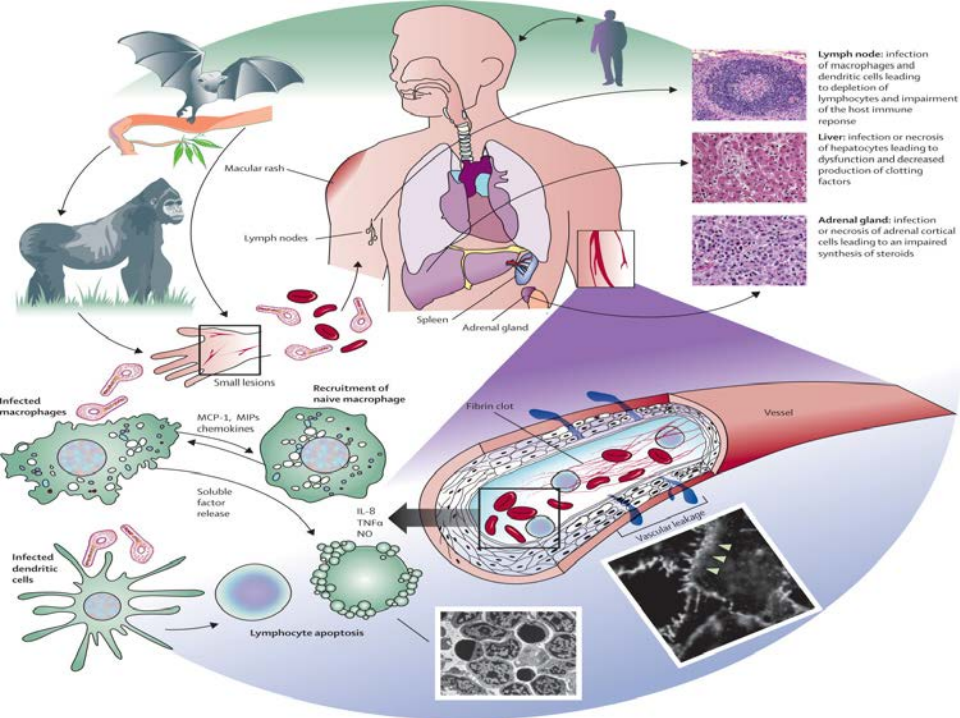
Costs \$2-8 per test, 100 of which fit in a portable cooler.

US DOD considering Liberia request for 3 more diagnostic labs (total 8) in country. Sierra Leone has 4, and Guinea, 3.

100 tests per day now, but expect 10,000 new cases per week by December, according to the WHO.

Need to get 70% of population with Ebola into isolation and care.

“With enough tests, we can shut it down.”
Without them, Ebola may be here to stay.



Liberia-awaiting child's test results



Oct. 31 not a holiday

Friday, Oct. 31 is a regular working day, Malacanang said yesterday.

Speaking over state-run *Atlatlat* radio, Presidential Communications Operations Office Secretary Herminio Coloma Jr. said the eve of All Saints' Day is not in the list of declared regular holidays and special non-working holidays.

Suspension of work would depend on the companies concerned, he added.

In Proclamation 655 in September 2013, President

Turn to Page 7

Poor health systems raise Ebola risk in Asia

SINGAPORE — The longer the Ebola outbreak rages in West Africa, the greater chance a traveler infected with the virus touches down in an Asian city.

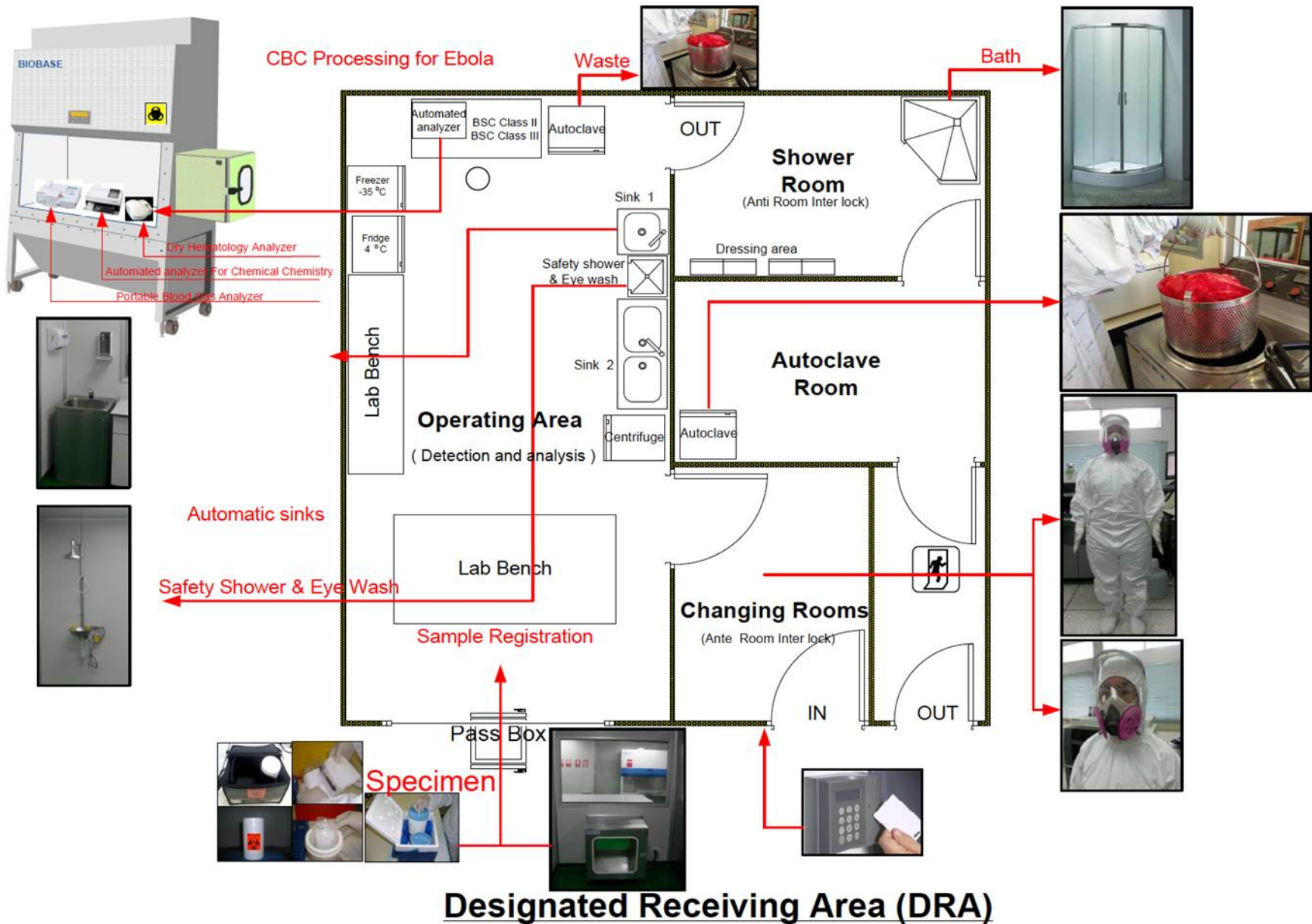
How quickly any case is detected — and the measures taken once it is — will determine whether the virus takes hold in a region where billions live in poverty and public

Turn to Page 8



Phi wants zero Ebola toll

Diagnostic Center



Point-of-Care Tests Established in Ebola Isolation Areas



A. Emory University Hospital Specialized Isolation Area⁹

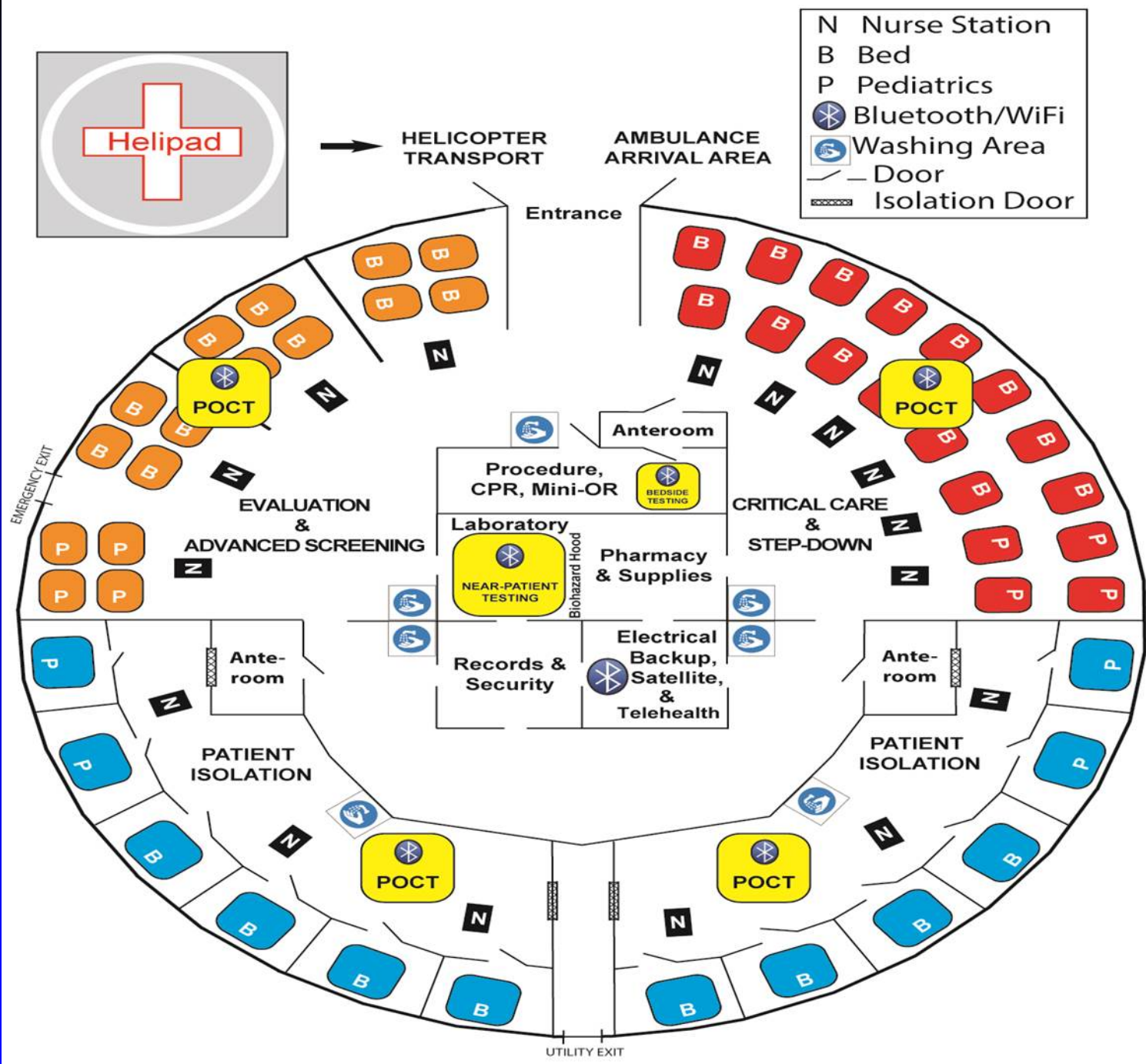
Manufacturer Website	Instrument	Test(s)
Abaxis www.abaxis.com	Piccolo Express	Chemistry profiles, Magnesium, Phosphate, liver enzyme assays, others available ^a
Instrumentation Laboratory www.instrumentationlaboratory.com	GEM Premier 4000	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , Glu, Lac, Hct, THb, CO-Oximetry, TBil
Siemens www.healthcare.siemens.com	CLINITEK Status automated urinalysis	Albumin, Bilirubin, Cr, Glu, Ketone, Leukocytes, Nitrite, pH, Protein, Specific Gravity, Urobilinogen, others available ^b
Hoffman-La Roche www.coaguChek.com	CoaguChek	PT/INR ^c
Sysmex www.sysmex.com	pocH-100i	CBC: WBC (3-part differential), RBC, Hb, Hct, MCV, MCH, MCHC, Platelets ^d
Alere www.alere.com	BinaxNOW	Malaria
BioFire Diagnostics www.biofiredx.com	FilmArray	Infectious diseases including Ebola ^e (see Table 1)

Point-of-Care Tests Established in Ebola Isolation Areas

B. University of Nebraska Medical Center Biocontainment BSL-3 Laboratory¹⁰

Manufacturer Website	Instrument/ Method	Test(s)
Abbott www.Abbott.com	i-Stat	G3+ cartridge (pH, pCO ₂ , pO ₂) & Chem8+ cartridge (Na ⁺ , K ⁺ , Cl ⁻ , TCO ₂ , Ca ⁺⁺ , Glu, UN, Cr, Hct)
International Technidyne Corp. www.itcmed.com	Hemochron Signature Elite	Citrate prothrombin time (PT), citrate-activated partial thromboplastin time (aPTT)
Slide Agglutination	Manual	Blood & serum antibody typing (for transfusion)
Slide Preparation	Manual	Malaria—modified for the slide to be fixed in methanol 15 min before delivering to Core Lab for staining & interpretation
NS	Rapid manual assay	HIV Ab/Ag
Urine Dipstick	Manual dipstick	For tests not on strip, specimen transferred with precautions to Core Lab for non-decapped Dxl800 & DXC800i ^f analysis
NS	RPR	Syphilis (card assay)

Alternate Care Facility for Ebola Triage and Care



Molecular Diagnostic Tests for Ebola

Instrument(s)

&/or Assay/Kit

Manufacturer

Principle

Sample(s)

Time to Results

FDA Status^a

LightMix
Cobas z480

rRT-PCR

Blood

Over 3 hrs

EUA
12/23/14

QIAamp Viral Kit
RealStar Filovirus:
ABI Prism 7500
SDS & Fast SDS
LightCycler 480 II
CFX96/Dx RT Sys.

rRT-PCR (Kit 1.0)

Blood, plasma

Varies
with
instrument

EUA
11/26/14
[also eligible
for WHO^b
procurement]

BioFire Defense
Biothreat-E
bioMerieux
[in 300 hospitals]

Film Array EZV
Auto'd. rRT-PCR

Blood, urine (if
matched to blood)

1 hr

EUA
10/25/14

ABI 7500 Fast Dx
LightCycler 480
JBAIDS

DOD EZ1 rRT-PCR
TaqMan Assay

Inactivated whole
blood & plasma

Varies
with
instrument

EUA
10/10/14

MagMax Pathogen
Kit, Dynal Bead Re.
ABI 7500 Fast Dx

CDC NP rRT-PCR
VP40 rRT-PCR

Blood, plasma,
serum, urine (if
matched)

NS

EUA
10/10/14

Nonomix
Corgenix & Tulane
University

Carbon nanotube
biosensor^c
Handheld
cartridge-based

Pinprick
capillary blood^c

15 min^c

No approval

Cepheid Xpert

Under development

Blood, saliva

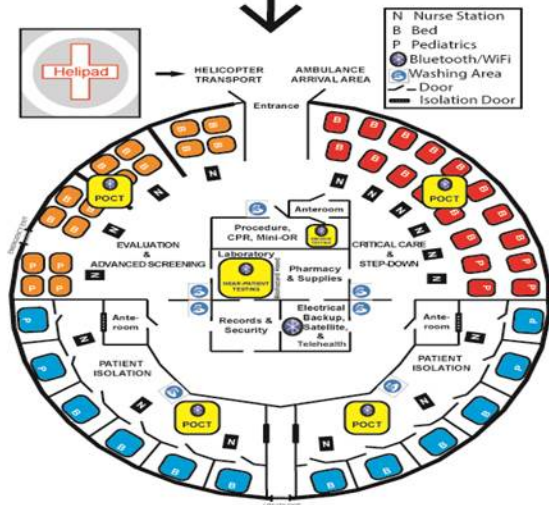
NS

No approval

SPATIAL CARE PATH™

SYMPTOMATIC PATIENT

RAPID MOLECULAR TESTING → TN, FN(t)



ALTERNATE CARE FACILITY

- Dynamic Segregation
- POC Coordinator
- Fully Equipped POCT
- Telehealth

HIGHER EFFICIENCY
LOWER RISK

OPTIMIZED POC
SOLUTION

COMMUNITY
RESILIENCE

HYBRID SOLUTION

EXPOSED PATIENT

CLINICAL EVALUATION
& DIAGNOSTIC TESTING
POC WBC, DIFFERENTIAL & PLATELET COUNT
INR, aPTT, Bleeding Time, ALT, & AST

LIMITED QUARANTINE
VACCINATION

HIGHLY
INFECTIOUS
DISEASE
BEDS
WITH
ANTEROOM

BLOOD SAMPLE
PROCESSED IN
ISOLATION UNIT &/OR
TRANSPORTED
TO REFERRAL LAB:
-CDC
-PUBLIC HEALTH

SLOWER RESPONSE
GREATER EXPENSE

INTEGRATED
PLANNING

SWN

◆ CONCLUSIONS AND RECOMMENDATIONS ◆

◆ POCT is improving global health,⁸⁹ and now, a global health problem is propelling POCT and its urgent implementation worldwide. World financial losses from Ebola and other outbreaks warrant investment,^{90,91} which we believe should be directed not just to vaccines, but also to the development POC molecular diagnostics, for which there is precedent.^{59,60,92-97}

◆ POC diagnostics should be available upstream for immigration screening, on cruise ships, in industrial sites abroad, and at other points of first encounter worldwide. Companion diagnostics, such as coagulopathy test clusters (PT/INR, D-dimer, fibrinogen, and platelets) and Ebola viral load assays, will streamline therapeutic monitoring downstream.

◆ SCPs consolidate process steps and ultimately will help stop the spread of outbreaks. Diagnostic centers with controlled environmental conditions placed along SCPs will motivate industry to respond to WHO calls⁷³ for robust diagnostic tests⁷⁴ and consolidate community efforts on a cost-effective broader scale.

◆ There are ~1,400 specialized isolation units in Hong Kong. Construction was motivated historically by the deaths of patients and healthcare workers from Severe Acute Respiratory Syndrome (“SARS”), which infected 1,800 and killed 299 people, and Avian Influenza (H1N1, H7N9).^{98,99} In Guangzhou, China, SARS killed 8,000.⁴⁰ These disasters *should not be repeated*.

◆ Adaptations in SE Asia and in individual U.S. hospitals, such as isolation areas in Atlanta, Dallas, New York, Bethesda (NIH), and Omaha, are notable, but not yet generating isolation bed capacity quickly enough to deal with potentially large numbers of Ebola cases or other infectious disease outbreaks in the future.

◆ CDC-approved Ebola hospital treatment centers are distributed unevenly. Ultimately, individual communities across America should be prepared to develop their own broad bases of response. ACFs with integrated logistics for community SWNs, as the CDC recommends be engaged, will allow U.S. communities to respond efficiently and effectively.

◆ Intrinsic to emerging POC culture^{56,82,83} is popular expectation of rapid diagnosis¹⁰⁰ of Ebola using disposable test strips, self-contained automated technologies, and other mobile approaches. Diagnostics that properly fulfills these expectations, while delivering ultra-high sensitivity, specificity, and predictive values will help stifle outbreaks.

◆ FAST POC will create self-knowledge, enabling people to take ownership, that is, interrupt the rapid spread of outbreaks, an impactful paradigm shift in public health to immediate diagnosis at points of need.

Global Point of Care

Strategies for Disasters, Emergencies, and Public Health Resilience

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UNDERSTANDING OF POINT OF CARE CULTURE IMPROVES RESILIENCE AND STANDARDS OF CARE IN LIMITED-RESOURCE COUNTRIES

GERALD J. KOST, YIMENG ZHOU, AND PRATHEEP KATIP

OVERVIEW

This chapter (a) defines point of care (POC) culture and reviews the historical impact of cultural aspects of medical care; (b) analyzes the underlying principles of POC culture in order to produce a future vision for POC testing (POCT); (c) describes how to characterize POC culture using formal subject surveys; (d) assesses objective and practical methods for implementing emerging POC technologies while simultaneously targeting value; (e) investigates four country settings where cultural attributes, including education, demography, eating habits, geography, politics, religion, and social science affect patient lifestyles, medical care, and health outcomes; and (f) with the aid of survey evidence showing subject preferences, prioritizes clever point of care, such as fingertip pulse oximeters and noninvasive skin autofluorescence (SAF) screening of prediabetes risk, in value propositions for nations seeking resilience for huge populations at risk. We investigated: (a) the status of POC culture in China and three ASEAN member states: Cambodia, Indonesia, and Thailand; (b) cultural factors based on preliminary survey results; and (c) the ability of new POC technologies to “fit” future medical problem solving, with emphasis on prediabetes and diabetes, for which we created a POCT-driven care path. Screening and testing directly in primary care facilitate unique rapid diagnosis, monitoring, and treatment. Often, POCT supplants the conventional clinical laboratory, which may be too distant, prohibitively expensive, or simply not available in limited-resource settings. Needs for POCT in these settings are striking, but fulfillment should be guided by thorough understanding of POC culture. Quick feedback and fast decision making by patients and physicians alike yield significant value that motivates necessary changes in patient lifestyles and physician interactions. Therefore, culturally sensitive technology assimilation ranks highly when addressing leadership challenges in nations adapting to increasing populations of both young and old persons,

despite scarcity of resources. Global harmonization of POC performance and astute cultural awareness accelerate favorable outcomes by improving the quality, usefulness, speed, and effectiveness of medical decision making. Worldwide outreach and carefully designed POC strategies in small-world networks (SWNs) enhance standards of care, including crisis standards of care for complex emergencies, natural disasters, and public health pandemics. At the same time, these strategies address evolving “newdemics” that burden nations economically. Despite episodic unexpected chaos from weather disasters and other natural calamities, predictable medical problems, such as obesity and prediabetes, should be addressed now at the point of need using point of care in proper cultural context with sound value propositions, while there is still time to avoid adverse and expensive consequences.

DEFINITIONS AND SCOPE

Broadly interpreted, culture, per se, has several practical definitions, including the beliefs, customs, and arts of a particular society, group, place, or time; a society that has its own ways of life; and a way of thinking, behaving, or working that exists in a place or organization. Point of care culture is medical empowerment of the individual and family nucleus integrated with norms, behaviors, beliefs, attitudes, expectations, POC technology, and outcomes (1). Point of care culture crosses the standard definitional dimensions of culture, because health is at the core of human existence, and people expect society to assure their good health. Expectations are strong beliefs that something will happen in the future. New technologies weigh heavily on expectations, and therefore, expectations should be assessed through frequent surveys designed to improve health with POCT.

POCT is medical testing at or near the site of care (2). It includes in vitro testing with handheld, portable, and transportable instruments, as well as self-monitoring and noninvasive scanning. A newdemic is a simultaneous set of unexpected and disruptive problems that affect the health of large numbers of individuals in a crowded world (3). A SWN is a loosely tied

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***Researching in Limited-Resource Rural
Thailand Settings—POC culture is medical
empowerment of the individual and family
nucleus integrated with norms, behaviors,
beliefs, attitudes, expectations, POC
technology, and outcomes—the final frontier!***

POLICY & GUIDELINES

- Introduced at a National POC Testing Forum in Kuala Lumpur, **Malaysia**, July, 2012
- Uniquely combines policy and guidelines in one document
- Endorsed by the **Malaysia** Ministry of Health—entire country
- One of the world's first nationally harmonized approaches to point-of-care testing, the new culture
- Needs extension based on “*Emergency and Disaster POC Testing*” (CLSI POCT16-coming!)
- **Thailand** MOPH national guidelines coming this year!
- **Philippines** in planning stage.



NATIONAL POINT OF CARE TESTING Policy and Guidelines



WHAT WE HAVE LEARNED!

- Needs assessment helps define the role of POCT in pandemics, complex emergencies, and disasters.
- Environmental stresses affect test results and must be avoided, so that POCT can be effective for decision-making in crises.
- Disaster caches should be designed and harmonized for collaborative use throughout the world and for pandemics.
- Spatial Care Paths™ start with the patient, position POCT optimally, and accelerate care, while we “tune the system” for cultural acceptance, so that national POCT policy and guidelines and fiscal planning will enhance and sustain community resilience.

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Appendix

- Recommendations from Abbott
 - HemoCue and POC WBC-Diff
- The FAST POC,* Education, and Instruction

* Facilitate-Access Self-Testing Point of Care

Recommendations from Abbott

- Abbott's diagnostic instruments are intended to provide safe operation when testing specimens containing infectious disease agents
- Instruments have not been specifically evaluated for testing specimens containing the Ebola virus; universal precautions used for other bloodborne pathogens should be used
- Decontamination and end-user maintenance of Abbott diagnostic instruments should be performed in accordance with the applicable operations manual
- The CDC recommends that appropriate hospital disinfectants be used, and that all waste be disposed of in accordance with facility-specific procedures and country, federal, and/or local regulations for biological waste
- In cases where patients have contracted Ebola, dedicated point-of-care instruments are recommended within the quarantined treatment area, and proper personal protective equipment (PPE) should be used for potential or known exposure
- In addition, consult and follow relevant country-specific health guidelines

i-STAT System Cartridge Menus

EC8+	EG7+	EG6+	CG8+	CHEM8+	6+
Sodium Potassium Chloride BUN Glucose pH PCO ₂ TCO ₂ * HCO ₃ * Base excess* Anion Gap* Hematocrit Hemoglobin*	Sodium Potassium iCalcium pH PCO ₂ PO ₂ TCO ₂ * HCO ₃ * Base excess* sO ₂ * Hematocrit Hemoglobin*	Sodium Potassium pH PCO ₂ PO ₂ TCO ₂ * HCO ₃ * Base excess* sO ₂ * Hematocrit Hemoglobin*	Sodium Potassium iCalcium Glucose pH PCO ₂ PO ₂ TCO ₂ * HCO ₃ * Base excess* sO ₂ * Hematocrit Hemoglobin*	Sodium Potassium Chloride BUN Glucose Creatinine iCalcium TCO ₂ * Anion Gap* Hematocrit Hemoglobin*	Sodium Potassium Chloride Glucose BUN Hematocrit Hemoglobin*
EC4+	E3+	G3+	CG4+	cTnl	BNP
Sodium Potassium Glucose Hematocrit Hemoglobin*	Sodium Potassium Hematocrit Hemoglobin*	pH PCO ₂ PO ₂ TCO ₂ * HCO ₃ * Base excess* sO ₂ *	pH PCO ₂ PO ₂ Lactate TCO ₂ * HCO ₃ * Base excess* sO ₂ *	Troponin I	B-type Natriuretic Peptide
G	CREA	ACT	PT/INR	CK-MB	
Glucose	Creatinine	Celite® or Kaolin Activated Clotting Time	Prothrombin time	Creatine kinase MB	
*Calculated					

HemoCue and Ebola: US and Africa Perspectives

(next three slides contributed by HemoCue)

- **WHO Recommendations**

- Limit the use of needles and other sharp objects as much as possible
- Limit the use of phlebotomy and laboratory testing to the minimum necessary for essential diagnostic evaluation and patient care

- **US Hospitals**

- Familiar with HemoCue POC technology for hemoglobin and glucose testing (waived)
- HemoCue WBC (Total White Count) Analyzer FDA cleared in 2007, moderately complex—niche market, as backup to bench top hematology analyzers

HemoCue and Ebola: US and Africa Perspectives

- **US Hospitals**

- September 2014, increased interest in WBC analyzer due to Ebola concerns
 - Minimize contamination to hospital staff, central laboratory, and medical instrumentation
 - Maximize containment—keep the patient and test specimens in one confined location in the hospital
 - Fast lab-accurate results—help physicians initiate immediate treatment for symptomatic patients
 - Analyzer portability—analyzers can be used where needed on battery power, including laminar air flow hoods, for maximum containment

Note: HemoCue POC Analyzers hold no restriction based on patient population being tested (e.g. critically ill, Emergency Department, etc.)

HemoCue and Ebola: US and Africa Perspectives

- **West Africa**

- Economic struggles limit availability of point-of-care testing
 - Little interest in WBC testing at the point-of-care
 - Limited use of point-of-care hemoglobin testing in isolation wards
- Priorities
 - Stopping the spread of the Ebola virus, disseminating information on protective routines
 - Appropriate care of those with the disease
- Interest in point-of-care testing limited to research and non-governmental related organizations (humanitarian missions)

Constituents of a FAST POC, Education, and Instruction Program

- ✘ Definition of the target disease, description of its pathophysiology, explanation of how it is transmitted to others, and precautions that will avoid exposure to others
- ✘ Explanation of what the self-contained cartridge and POC device are, how the test method works, and why quality control (if any) is necessary, all in the local language
- ✘ Proof of ultra-high sensitivity, specificity, and positive and negative predictive values
- ✘ Statement of FDA approval (in the U.S.) written to have high educational and self-help value
- ✘ Listing of device and peripherals, contraindications to use, warnings of biohazards, limitations of the assay, exceptions to interpretation of results, environmental limits for storage and operation, and low-high indicators for temperature infractions
- ✘ Notice of same-day use of reagents after opening them, if appropriate
- ✘ Ample visual logistics, such as schematics of the POC device and its components, pictures of the testing process, "stop" and "go" signs when process steps are timed, and video demonstrations
- ✘ Description of a few easy steps taken to perform testing, the safety of the process, and required specimen containment, both printed and available in speech online
- ✘ Instructions for simple, yet reliable reading of test results
- ✘ Patient registration, code (PIN) number, transport instructions, packaging, and technical access to a diagnostic center for analysis, if that modality is used
- ✘ Discussion of how to interpret positives and negatives, or in the case of self-contained sealed cartridges taken to a diagnostic center, how to get results quickly with professional explanation
- ✘ Clean-up procedures in the event of spillage of the patient sample, the reagents, or quality control solutions (if QC is included), and emergency contact information

END